Project Study Information

IRAS Information

IRAS Form	Reference: 99/AA/1234	IRAS Version: 5.9.1
Short title for project:	PROTECT-AEGIS	

Key people and organisations

Chief investigator:	Tom Abbott
Project deputy:	salma Begum
Project funder:	National Institute of Health and Care Research

Project scope

CTIMP questions

Provide the project EudraCT ID. The required format is ####-######-##	
Will any research sites in this study be NHS organisations?	Yes
Does the study involve use of any ionising radiation?	No
Will you be taking new OR existing human tissue samples (or other human biological samples)?	No
Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?	No
Do you plan to include any participants who are children?	No
Do you plan to request clinical research network support? Ticking yes will allow IRAS to share the status of your application with clinical research networks in the future.	No
Do you plan to include any participants who are prisoners or young offenders?	No
Proposed Study End Date	30/06/2027

A. Administrative Details

1. In which countries of the UK will the research sites be located? (Tick all that apply)

- ☑ England
- ☑ Scotland
- ☐ Wales
- ☐ Northern Ireland

2. In which country of the UK will the lead NHS R&D office be located?

England

3. Will any research sites in this study be NHS organisations?
Please note details entered here will be matched to the same question on Project details screen

◉Yes ○No

3a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

○Yes ◉No

3b. Have you, or do you intend to, make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

◉Yes ○No

4. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○Yes ◉No

5. Is this a commercially sponsored Phase 1 or Phase 1/2a trial involving healthy volunteers?

○Yes ◉No

6. Full title of the research
Details entered here will be entered into Medicines Information A3

Analgesia with ibuprofen for patients undergoing elective major Gastro-Intestinal Surgery

7. Is this application linked to a previous study or another current application?

◉Yes ○No

7a. Please give brief details and reference numbers

This trial is appendix 1 of the PROTECT platform trial under CWOW number 1008776

8. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○Yes ◉No

9. Lay Summary of the study

After the participant's operation, they will receive one of two study treatments, either ibuprofen and standard pain control or only standard pain control. Standard pain control usually involves morphine-like medicines, and local anaesthetic which can be placed straight into the surgical wound, or given through an epidural. Paracetamol is also widely used. This decision will be made at random and neither the participant nor their doctor will be able to decide which study treatment they receive. If participants are in the ibuprofen group, they will be given ibuprofen along with standard pain control and all their usual medications for five days after surgery. In the standard care group, participants will receive the standard pain management for their hospital without ibuprofen. If participants are in the ibuprofen arm, they will also receive medication to prevent stomach ulcers. All of their other treatments will be the same regardless of which study treatment they get. Their doctors at the hospital will be aware that they are in this study and will be closely monitored throughout their hospital stay. If necessary, adjustments to their treatment will be made to make sure they are safe. The GP will also be informed of their participation in the study so they are aware the patient might have received ibuprofen during their hospital stay. Participants will also be asked some questions about their health before and after their operation, which will be online or by telephone if at home, and face to face if they still in hospital. We will record information about any pain they experience on the first five days after surgery, which will take about two minutes each day. If participants have a carer or proxy, they would be welcome to help answer these questions. The last time we contact participants will be 30 days after their operation.

10. In which aspects of the research process have you actively involved or will you involve patients service users and/ or their carers or members of the public?

☑ Design of the research
☐ Management of the research
☐ Undertaking the research
☐ Analysis of results
☐ Dissemination of findings
☐ None of the above

11. Give details of involvement, or if none please justify the absence of involvement.

Patients have been involved through the design of the PROTECT-AEGIS trial, advising on the ethics of research involving patients making life changing decisions, patients' likely values and expectations of surgical treatments, our wider strategy for involving patients as both investigators and research participants, and our implementation plan. In addition to our patient co-applicants, proposals related to trial activity have been constantly reviewed in detail by the Royal College of Anaesthetists Patient & Public Involvement group. We have fully incorporated several of their suggestions into this programme including strategies to improve patient participants' experience of this research, and the development of a patient advisory group, who review and provide feedback on patient facing documents.

12. Is the trial a Complex Innovative Design (CID) trial?

◉Yes ○No

12a. If yes, select the trial methodology

Platform trial

B. Research Procedures, Risks and Benefits

1. Non-clinical interventions
(Please complete for each intervention/procedure as follows)

1: Interventions/procedures to be received by each participant as part of the research protocol
2: Number of interventions/procedures which are part of standard care
3: Number of interventions/procedures which are additional to standard care
4: Total number of interventions/procedures
5: Average time taken per intervention/procedure (minutes, hours or days)
6: Details of who will conduct the intervention/procedure and where it will take place

1	2	3	4	5	6
Eligibility	0	1	1	15	Principal investigator or delegated doctor
Informed consent	0	1	1	15	Appropriately trained member of the research team
Demographics	1	1	2	5	Appropriately trained member of the research team
Review of medical notes	0	9	9	15	Appropriately trained member of the research team
Randomisation	0	1	1	10	Delegated member of the research team
OBAS and NRS pain scores	0	5	5	10	Delegated member of the research team
Safety review	0	5	5	10	Delegated member of the research team
Data collection	0	9	9	10	Delegated member of the research team

2. Clinical interventions
(Please complete for each intervention/procedure as follows)

1: Interventions/procedures to be received by each participant as part of the research protocol
2: Number of interventions/procedures which are part of standard care
3: Number of interventions/procedures which are additional to standard care
4: Total number of interventions/procedures
5: Average time taken per intervention/procedure (minutes, hours or days)
6: Details of who will conduct the intervention/procedure and where it will take place

1	2	3	4	5	6
Administration of standard of care and oral ibuprofen	5	0	5	10	A member of the direct care team
Administration of standard of care	0	5	0	5	A member of the direct care team

3. Will you withhold an intervention, medicine or procedure, which would normally be considered a part of routine care?

○Yes ◉No

4. What are the potential risks and burdens for research participants and how will you minimise them?

Ibuprofen will be used within its license and only patients known to be at low risk of potential side effects of NSAIDs will be enrolled.

5. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○Yes ◉No

6. What arrangements are being made for continued provision of the investigational medicinal product for participants, if appropriate, once the research has finished? If the intention is to not provide IMP to participants when the trial has completed, this must be clearly justified.

There will be no continued provision of intervention after the research has finished. Ibuprofen is widely available to patients.

7. Will you inform the participants' General Practitioner that they are taking part in the trial? (and/or any other healthcare professional responsible for their care).

◉Yes ○No

8. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

No

9. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?

If a participant is unable to read or sign the informed consent form but has capacity to give consent, this can be provided on the participant's behalf by a witness. A statement will be included in the consent form explaining that the participant understood the information and informed consent was given freely.

If translation of consent materials is required this will be done via the recruiting site's interpreting service, which may be an in-person interpreter, or a video/telephone interpreter service (e.g. Language Line). The details of the interpreter should be recorded in the participant's medical record, in addition to the standard record of the consent process. The use of friends or family members for translation of consent materials is prohibited. We will develop non-English ICF and PIS as we learn more about those most in demand for the PROTECT eligible patient population.

10. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

☑ Access to medical records by those outside the direct care team
☐ Electronic transfer by magnetic or optical media, email or computer networks
☐ Sharing of personal data with other organisations
☐ Export of personal data outside the EEA
☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
☐ Publication of direct quotations from respondents
☐ Publication of data that might allow identification of individuals
☐ Use of audio/visual recording devices
☑ Storage of personal data on any of the following:
☑ Manual files (includes paper or film)
☑ NHS computers
☐ Social Care Service computers
☐ Home or other personal computers
☑ University computers
☐ Private company computers
☐ Laptop computers

11. Please describe the physical security arrangements for storage of personal data during the study

The database will be hosted within a Trusted Research Environment within the UK Secure Research Platform (UKSeRP), on a

secure server at Swansea University. All data entered will be encrypted in transit between the client and server. Security of the electronic data entry system is maintained through user-names and individual permissions approved centrally by the study trial mangers. All electronic
information will be held on servers located in access-controlled server rooms, backed up to a secure location on a regular basis. Central back-up procedures are in place. Storage and handling of confidential trial data and documents will be in accordance with the Data Protection Act (2018) and General Data Protection Regulations. All data will be handled in accordance with the Data Protection Act (2018) and General Data Protection Regulations.

12. How will you ensure the confidentiality of personal data?

Participants enrolled into the study will be allocated a unique study identifier generated by the PROTECT database. The participant's full name, sex at birth, date of birth, NHS number (UK) and postcode will be entered on to the secure data entry web portal to allow tracing through national records. The personal data recorded on all documents will be regarded as confidential. All participant related trial documents are confidential and must be stored securely at each hospital (e.g. participant consent forms). The PI must ensure that patient confidentiality is maintained at all times. The Sponsor will ensure that all participating partner organisations will maintain the confidentiality of all subject data and will not reproduce or disclose any information by which subjects could be identified, other than reporting of serious adverse events. Participant identifiable information must not be stored or transported on any portable device (e.g., laptops, memory sticks, CD / DVDs) unless it is encrypted. Similarly, data must not be sent electronically if it is not subject to end-to-end encryption. In the event that Patient Identifiable Data needs to be transferred between authorized users, this will occur by email from @nhs.net to @nhs.net accounts, or using authorised secure file transfer systems. Information regarding study participants will be kept confidential and managed in accordance with the Data Protection Act (2018), the UK Policy Framework for Health and Social Care and Research Ethics Committee approval. All study data will be stored in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments and the Data Protection Act. Study data will be archived in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments, and as defined in the Sponsor SOP for archiving

13. Who will have access to participants' personal data during the study?

Only members of the direct care team within each NHS site are entitled to have access to patients' medical records. Direct access will be granted to authorised representatives from the Sponsor, host institution, and the regulatory authorities to permit study-related monitoring, audits, and inspections.

14. Where will the data generated by the study be analysed and by whom?

The data controller for the PROTECT database will be Queen Mary University of London and data processors will be Swansea University (including the SAIL Databank and UK Secure Research platform) based in Wales, UK. The principal document guiding statistical analysis is a statistical analysis plan (SAP). A full statistical analysis plan will be developed and signed off prior to unblinding and final analysis of this comparison. All signed off versions of SAPs will be made publicly available and finalised before statistical analysis is undertaken. Any subsequent changes to the SAP or post-hoc analyses will be justified and documented in the final report.

15. How long will personal data be stored or accessed after the study has ended?

Over 3 years

16. For how long will you store research data generated by the study?

25 years

17. Please give details of the long term arrangements for storage of research data after the study has ended.

All study data will be stored in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments and the Data Protection Act. Study data will be archived in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments, and as defined in the Sponsor SOP for archiving. The sites are responsible for maintaining and archiving all local records including the investigator site file and any paper CRFs in accordance with the Sponsor's SOP. These records should be archived together once authorisation has been given by the sponsor. It is the responsibility of the PI to ensure a full set of records is collated and documented. In addition, source documentation should be retained, as per local policy, for the duration of the archiving period.

18. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when

publishing the results?

Only de-identified data will be used for the analysis of the data. No identifiable information will be used in the reporting of study results

19. Will individual researchers receive any personal payment over and above normal salary or any other benefits or incentives for taking part in this research?

○Yes ◉No

20. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○Yes ◉No

21. Please confirm the arrangements for registration of this trial on a public database.

Trial will be registered on a publicly accessible database

C. Transparency

1. How do you intend to report and disseminate the results of the study?

☑ Peer reviewed scientific journals
☐ Internal report
☐ Conference presentation
☑ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other

2. How will you enable sharing of study data with others?

Data arising from this research will be made available to the scientific community in a timely and responsible manner.

3. How will you enable sharing of tissue samples and associated data with others?

Not applicable

4. How and when will you inform participants of the study results?
If there will be no arrangements in place to inform partcipants please justify this.

Results of the study will be made publicly available via the HRA website and ISRCTN

5. Point of Contact for Publication

Chief Investigator

D. Scientific and Statistical Review

1. How has the scientific quality of the trial been assessed?

☑ Independent external review
☐ Review within a company
☐ Review within a multi−centre research group
☑ Review within the Chief Investigator's institution or host organisation
☐ Other

2. Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

The proposal was peer reviewed by internal and external experts during the funding process. Since securing the award, the protocol has since been further reviewed during the study design process.

3. How have the statistical aspects of the research been reviewed?

☐ Review by independent statistician commissioned by funder or sponsor
☐ Other review by independent statistician
☐ Review by company statistician
☑ Review by a statistician within the Chief Investigator's institution
☐ Review by a statistician within the research team or multi−centre group
☐ Review by educational supervisor
☐ Other review by individual with relevant statistical expertise

4. In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title
Dr

Surname
Hamborg

Forename/Initials
Tom

Department
Wolfson Institute of Population Health

Institution
Queen Mary University of London

Street
Yvonne Carter Building

City
London

Country

Post code
E1 2AB

Email
t.hamborg@qmul.ac.uk

Telephone

Mobile

5. How was the sample size decided upon?

We have selected a feasibility sample size of 200 patients in 10 NHS hospitals over a 12-month recruitment period providing robust estimates of patient and clinician willingness to participate. This will also provide robust data on rates of possible treatment harms which are a key driver of the sample size for the main trial. The 95% confidence interval width for feasibility objective rate estimates is at most are +/- 7.1% with a sample size of 200.

E. Management of the Research

1. Sponsor Organisation status

Academic

2. Is this study?

◯ Single Centre
◉ Multi Centre

3. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

3a. Other insurance or indemnity arrangements (please Specify)

Sponsor's indemnity will apply

4. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

4a. Other insurance or indemnity arrangements (please Specify)

Sponsor's indemnity will apply.

5. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/ collaborators arising from harm to participants in the conduct of the research?

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

6. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

◉ Yes ◯ No

6a. Please give details of the compensation policy:

Queen Mary University of London insurance offer a "no-fault" compensation where, on the balance of probability, the harm was likely caused by the trial procedures.

F. Ionising Radiation

1. Does the study involve exposures to radioactive materials?

◯ Yes ◉ No

2. Does the study involve other diagnostic or therapeutic ionising radiation?

◯ Yes ◉ No

3. Has the trial been authorised by a Clinical Radiation Expert (CRE) and a Medical Physics Expert (MPE)?

○Yes ◉No

4. What are the risks associated with ionising radiation exposures within the trial?

n/a

G. Tissue

1. List the human biological material/tissue samples which will be removed and/or stored as part of the research

None, not applicable.

2. Please explain what licensing arrangements apply to the procurement, processing, distribution or import of the tissues and cells to be used in the research.

n/a

3. If you are using existing tissue samples where will the samples be obtained from?

☐ NHS pathology department(s)/diagnostic archive(s)
☐ Other research tissue bank(s) or sample collection(s)

4. Please give details of where the samples will be stored, who will have access and the custodial arrangements.

n/a

5. If you are obtaining existing tissue samples, will there be consent in place?

Select..

6. What will happen to the samples at the end of the research?

☐ Transfer to research tissue bank
☐ Storage by research team pending ethical approval for use in another project
☐ Storage by research team as part of a new research tissue bank
☐ Storage by research team of biological material which is not “relevant material” for the purposes of the Human Tissue Act
☐ Disposal in accordance with the Human Tissue Authority’s Code of Practice
☑ Other
☐ Not yet known

7. Please give further details of the proposed arrangements:

n/a

H. Recruitment and Informed Consent Procedure

1. How will potential participants be identified?

Potentially eligible participants will be identified by screening operating theatre lists, electronic patient records, etc.

2. What resources will be used for recruitment?

The consent process may use either electronic (eConsent) or paper-based consent, with eConsent the preferred method where possible. The consent process itself can take place either face-to-face or using a locally approved remote method (phone, video call,

etc.). All potential participants will be provided with a copy of the latest versions of the patient information sheet and informed consent form together with an explanation of the aims, methods, anticipated benefits and potential hazards of participation. This will be done either in person, using electronic methods, or by post. The patients will be given the opportunity to ask questions about the study by a qualified healthcare professional who is a member of the research team. Where possible all patients will be given a minimum of 24 hours between the time they are approached about the trial and the time when consent is given. For those patients who have not been contacted face-to-face, the signed consent form will be returned via electronic methods or by post and countersigned a member of the research team.

3. Will identification of potential participants involve access to identifiable information?

◉Yes ○No

3a. If yes, describe what measures will be in place to confirm that access to this information will be lawful.

Potentially eligible participants will be screened by the delegated members of the direct care team for entry into the study in accordance to the PROTECT master protocol. Research delivery staff embedded within NHS trusts should be regarded as part of the direct care team. Research is a routine part of effective healthcare and will be subject to the same information governance requirements in this respect. Potentially eligible participants will be screened by the direct care team for entry into the study in accordance to the PROTECT master protocol. Research delivery staff embedded within NHS trusts should be regarded as part of the direct care team. Research is a routine part of effective healthcare and will be subject to the same information governance requirements in this respect.

4. Who will be approaching potential participants and who will be obtaining informed consent?

The PI has overall responsibility for the informed consent of participants at their site and will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained, and competent to participate according to the ethically approved protocol, principles of GCP and Declaration of Helsinki. If delegation of consent occurs, then details will be provided in the site delegation log. The PI or appropriately trained delegate e.g. research nurse, will obtain consent from each patient prior to participation in this trial. All staff taking consent will be trained in taking consent and this will be evidenced on the local delegation log(s). They will also have appropriate GCP training. If consent is not taken by a medically qualified person, the PI or delegated doctor will confirm eligibility beforehand and the informed consent form will be verified in a timely manner.

5. How, when and where will informed consent be obtained?

For patients who have chosen eConsent, the form may be completed on a computer, smartphone or tablet/electronic device. Informed consent will be recorded by means of a dated participant electronic signature before they may enter the trial. The signature will be generated either by a finger tracing across a tablet device, or using an electronic stylus on a tablet device or using a mouse dragging the cursor across the screen – all methods are to be used as if signing with a traditional pen. The member of the research team taking consent will then add their own dated electronic signature to the consent form. One copy of the consent form will be sent to the participant using electronic methods (e.g. email), and the hospital site will be able to download a copy of the consent form from the PROTECT online e-Consent system and/or trial database.

6. How long will potential participants (or their legal representative) be given to decide whether to participate?

Where possible all patients will be given a minimum of 24 hours between the time they are approached about the trial and the time when consent is given.

7. How will it be assured that potential participants (or their legal representative) have understood the information and that consent is informed?

The study will be explained to the participant by a research team member and opportunities will be given for patients or their representatives to ask questions regarding the research by a doctor and assurances will be taken from the participant that they have understood the patient information sheet and that they consent to participate in the study. This will be documented in the patient's medical records.

8. What arrangements are in place to obtain informed consent from potential participants (or their legal representative) who do not speak English?

If a participant is unable to read or sign the informed consent form but has capacity to give consent, this can be provided on the

participant's behalf by a witness. A statement will be included in the consent form explaining that the participant understood the information and informed consent was given freely.
If translation of consent materials is required this will be done via the recruiting site's interpreting service, which may be an in-person interpreter, or a video/telephone interpreter service (e.g. Language Line). The details of the interpreter should be recorded on the consent form and in the participant's medical record, in addition to the standard record of the consent process. The use of friends or family members for translation of consent materials is prohibited. We will develop non-English ICF and PIS as we learn more about those most in demand for the PROTECT eligible patient population .

9. How will it be ensured that participants can withdraw their consent at any point?

Participants may decline to continue to take part in the platform, either from individual comparisons if they are recruited to multiple, or from the whole platform if they want to withdraw entirely, at any time without prejudice. A decision to decline or withdraw consent will not affect the standard of care the participant receives. Participants can withdraw their consent by contacting the research team, with the contact details provided on the PIS. Participants who decline further contact can withdraw entirely from the platform. In this case, a withdrawal form will be completed and no further data will be collected from that participant. Participants will be given the option to continue their participation in the platform, allowing the research team to use any routinely collected data through the data linkages described in the master protocol and any relevant appendices but to decline further individual (in person) data collection by the recruiting site or central research teams . If participants are enrolled in multiple comparisons, they may wish to withdraw from a particular comparison but continue in another. In this case, the same procedures will be followed as above but only for the comparison that they wish to withdraw from. Upon withdrawal of the participant, any source data recorded up to the time of withdrawal will be collected and retained by the research team and included in the final analysis. Once withdrawn, the local clinical team will be notified and asked to clarify and ensure further care needs with the participant. Those participants with a recorded outcome will be included in any analyses (on an intention to treat (ITT) basis for interventional comparisons).

10. Please provide any further information, in relation to the procedure for recruitment and informed consent for the clinical trial, which has not been provided elsewhere.

n/a

11. Provide a clear indication of what the first act of recruitment will be.

The consent process can take place either face-to-face or using a locally approved remote method (phone, video call, etc.) prior to their surgery date. All potential participants will be provided with a copy of the latest versions of the Patient Information Sheet (PIS) and Informed Consent Form (ICF) together with an explanation of the aims, methods, anticipated benefits and potential hazards of participation. This will be done either in person, using electronic methods, or by post.

13. Clinical Trials in Emergency Situations

13a. Will the trial recruit participants in an emergency situation whereby consent from the participant cannot be sought or a legal representative cannot be consulted prior to the participant being recruited into the trial?

○Yes ◉No

15. Impartial Witness

15a. Is the trial likely to include participants who are unable to sign the consent form and therefore an impartial witness would be required?

◉Yes ○No

15b. Why is it expected that an impartial witness might be required?

If a participant is unable to read or sign the informed consent form but has capacity to give consent, this can be provided on the participant's behalf by a witness whose details and signature will be provided in the participant's consent form.

15c. How will an impartial witness be identified?

The process for identifying a suitable witness should be as per HRA & REC guidelines.

15d. How will it be known that the potential participant gives their informed consent?

This will be confirmed by the impartial witness in the consent form.

16. Cluster Trials

16a. Will the trial involve the recruitment and allocation of an IMP to groups of participants rather than individual participants (cluster trial)?

○Yes ◉No

I. Payment of Compensation

1. Will payment or compensation be offered?

○Yes ◉No

1c. If not, please explain why not

n/a

2. Describe arrangements for how any payment or compensation will be paid/provided

n/a

3. Are there any conditions attached to the payment or compensation?

○Yes ◉No

A. Trial Identification

A1. National Competent Authority

UK - MHRA

A2. European Clinical Trials Database (EudraCT) number

—

A3. Full title of the trial

Please note details entered here will be inserted into Study Information A6

Analgesia with ibuprofen for patients undergoing elective major Gastro-Intestinal Surgery

A3-1. Title of the trial for lay people, in easily understood, i.e. non-technical, language

Pain management using ibuprofen after major gut surgery

A3-2. Name or abbreviated title of the trial where available

Please return to Update project details if you need to amend the short project title entered here.

PROTECT-AEGIS

A4-1. Sponsor's protocol code number:

1.0

A4-2. Sponsor's protocol version:

1.0

A4-3. Sponsor's protocol date:

11 November, 2024

A5-1. ISRCTN number

—

A5-2. ClinicalTrials.gov number

—

A5-3. WHO Universal Trial Reference Number (UTRN)

—

A5-4. Other Identifiers:

Name	Identifier
No items	

A6. Is this a resubmission?

○Yes ◉No

A6-1. Indicate the resubmission letter or else select 'First submission'

First Submission

A7. Is the trial part of a Paediatric Investigation Plan?

◯Yes ◉No ◯Not Answered

B. Identification of the sponsor responsible for the request

B. Sponsor Identification

B1. Sponsor

B1-1 Name of organisation

Queen Mary University of London

B1-2 Name of person to contact:

B1-2-1 Given Name	B1-2-2 Middle Name	B1-2-3 Family Name
Mays		Jawad

Address

Street Address	Town/City
Dept W, 69-89 Mile End Road	London
Post Code	**Country**
E1 4UJ	United Kingdom

Telephone Number

Country Dialing Prefix	Local Area Code	Phone Number	Extension
+44	0207	882	7275

Fax Number

Country Dialing Prefix	Local Area Code	Phone Number

Extension

E-mail

Research.governance@qmul.ac.uk

B3. Status of the Sponsor

B3. Status of the Sponsor:

Non-Commercial

B4. Source(s) of Monetary or Material Support for the clinical trial (repeat as necessary)

B4-1. Name of organisation	B4-2. Country
National Institute of Health and care Research - Research for patient benefit	United Kingdom

B5. Contact point designated by the sponsor for further information on the trial

B5-1 Name of organisation

Queen Mary University of London

B5-2 Functional name of contact point

Dr Mays Jawad

Address

Street Address

Dept W, 69-89 Mile End Road

Town/City

London

Post Code

E1 4UJ

Country

United Kingdom

Telephone Number

Country Dialing Prefix	Local Area Code	Phone Number	Extension
+44	0207	882	7275

Fax Number

Country Dialing Prefix Local Area Code Phone Number

Extension

E-mail

research.governance@qmul.ac.uk

C. Applicant Identification

C1. Request for Authorization to Competent Authority

C1-1, C1-2, C1-3 Who is responsible for the Clinical Authorization Application?

The sponsor

C1-4 Complete the details of the applicant below even if they are provided elsewhere on the form

C1-4-1 Name of organisation

Queen Mary University of London

C1-4-2 Name of person to contact:

C1-4-2-1 Given Name

May

C1-4-2-2 Middle Name

C1-4-2-3 Family Name

Jawad

Address

Street Address
Dept W, 69-89 Mile End Road

Town/City
London

Post Code
E1 4UJ

Country
United Kingdom

Telephone Number

Country Dialing Prefix	Local Area Code	Phone Number	Extension
+44	0207	882	7275

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail
Research.governance@qmul.ac.uk

C1-5 Request to receive a copy of the CTA data XML

C1-5-1 Do you want a xml file copy of the CTA form data saved on EudraCT?

◉Yes ○No ○Not Answered

C1-5-1-1 E-mail

E-mail
Research.governance@qmul.ac.uk

C1-5-1-2 Secure E-mail (EudraLink account)?

○Yes ◉No ○Not Answered

C2. Request for Opinion of the Ethics Committee

C2-1, C2-2, C2-3, C2-4 Applicant Identification
Coordinating investigator (for multicentre trial)

C2-5 Complete the details of the applicant below even if they are provided else where on the form

C2-5-1 Organisation
Queen Mary University of London

C2-5-2 Name of contact person

C2-5-2-1 Given Name
Tom

C2-5-2-2 Middle Name

C2-5-2-3 Family Name
Abbott

Address

Street Address
Royal London Hospital

Town/City
London

Post Code

Country

E1 1FR

United Kingdom

Telephone Number

Country Dialing Prefix	Local Area Code	Phone Number	Extension
+44	0203	594	0348

Fax Number

Country Dialing Prefix	Local Area Code	Phone Number	Extension

E-mail

t.abbot@qmul.ac.uk

D. Investigational Medicinal Products

D. Investigational Medicinal Products

IMP Name:

PR1

D1/D2. IMP Identification and Status Details

D1-2/D1-3. Investigational medicinal product category:

Comparator

D2. Status of the IMP

D2-1. Does the IMP to be used in the trial have a marketing authorisation?

◉Yes ○No ○Not Answered

D2-1-1-1. Trade Name:

Ibuprofen

D2-1-1-1-1. EV Product Code

not available

D2-1-1-2. Name of the MA holder:

Flamingo Pharma UK Ltd

D2-1-1-3. MA Number (if MA granted by a Member State)

PL 43461/0005

D2-1-1-4. Is the IMP modified in relation to its MA?

○Yes ◉No ○Not Answered

D2-1-2. Which country granted the MA?

United Kingdom

D2-1-2-1. Is this the Member state concerned with this application?

◉Yes ○No ○Not Answered

D2-2. IMP to be used in the CT has a marketing authorisation

D2-2. For situations where the IMP to be used in the CT has a Marketing Authorisation in the Member State concerned but the protocol allows that any brand of the IMP with a Marketing Authorisation in that Member State be administered to the trial subjects and it is not possible to clearly identify the IMP(s) in advance of the trial start

D2-2-1. In the protocol, is treatment defined only by active substance?

◉Yes○No○Not Answered

D2-2-1-1. If 'Yes', give active substance in D3-8 or D3-9

D2-2-2. In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS?

○Yes◉No○Not Answered

D2-2-3. The products to be administered as IMPs are defined as belonging to an ATC group

○Yes◉No○Not Answered

D2-2-4. Other:

○Yes◉No○Not Answered

D2-3. IMPD submitted / D2-4. IMP previously authorised / D2-5. IMP designated as an Orphan drug / D2-6. Subject of Scientific Advice

D2-3-1, D2-3-2 and D2-3-3: only one may be answered 'Yes' and the others must be answered 'No'

D2-3-1. Full IMPD

○Yes◉No○Not Answered

D2-3-2. Simplified IMPD

○Yes◉No○Not Answered

D2-3-3. Summary of product characteristics (SmPC) only

◉Yes○No○Not Answered

D2-4. Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community?

○Yes◉No○Not Answered

D2-5. Has the IMP been designated in this indication as an orphan drug in the Community?

○Yes◉No○Not Answered

D2-6. Has the IMP been the subject of scientific advice related to this clinical trial?

○Yes○No◉Not Answered

D3. Description of IMP

D3-1. Product name where applicable

Ibuprofen

D3-2. Product code where applicable

D3-3. ATC codes, if officially registered

M01AE01

D3-4. Pharmaceutical Form

Tablet

D3-4-1. Is this a specific paediatric formulation?

◯Yes◉No◯Not Answered

D3-5. Maximum duration of treatment of a subject according to the protocol

400mg three times a day for 5 days

Note: Content will be enabled for D3-6-1 and D3-6-2 only E7-1-1 is selected

D3-6. Dose allowed

D3-6-1. For first trial only

D3-6-1. First dose for first-in-human clinical trial

D3-6-1. Specify per day or total

◯Per day◯Total◯Not Answered

D3-6-1. Specify total dose number

D3-6-1. Specify total dose units

Select..

D3-6-1. Route of administration (relevant to the first dose)

Select..

D3-6-2. For all trials

D3-6-2. Maximum dose allowed

D3-6-2. Specify per day or total

◉Per day◯Total◯Not Answered

D3-6-2. Specify total dose number

1200

D3-6-2. Specify total dose units

mg milligram(s)

D3-6-2. Route of administration (relevant to the maximum dose)

Oral use

D3-7. Routes of administration for this IMP

Selected Routes of administration
Oral use

D3-8. Active substances

D3-8. Name of Active Substance (INN or proposed INN if available)

Ibuprofen

D3-9-1. CAS Number:

15687-27-1

D3-9-2. Current Sponsor Code:

n/a

D3-9-3. Other Descriptive Name:

n/a

D3-9-4. EudraVigilance Substance Code (if known):

n/a

D3-9-5. Full Molecular Formula

C13H18O2

D3-9-6. Chemical/Biological Description of the Active Substance

Ibuprofen

D3-10. *Strength*

D3-10-1. Concentration Unit:

mg milligram(s)

D3-10-2. Concentration Type:

Equal

D3-10-3. Concentration Number (only use both fields for range):

400 mg

D3-10-3. Concentration Number (only use both fields for range):

n/a

D3-11. Type of IMP

Does the IMP contain an active substance:

D3-11-1. Of chemical origin?

◉Yes ○No ○Not Answered

D3-11-2. Of biological/biotechnological origin? (other than Advanced Therapy IMP (ATIMP))

○Yes ◉No ○Not Answered

Is this IMP a:

D3-11-3. Advanced Therapy IMP (ATIMP)?

○Yes ◉No ○Not Answered

D3-11-4. Combination product that includes a device, but does not involve an Advanced Therapy

◯Yes◉No◯Not Answered

D3-11-5. Radiopharmaceutical medicinal product?

◯Yes◉No◯Not Answered

D3-11-6. Immunological medical product (eg vaccine, allergen, immune serum)?

◯Yes◉No◯Not Answered

D3-11-7. Plasma derived medicinal product?

◯Yes◉No◯Not Answered

D3-11-8. Extractive medicinal product?

◯Yes◉No◯Not Answered

D3-11-9. Recombinant medicinal product?

◯Yes◉No◯Not Answered

D3-11-10. Medicinal product containing genetically modified organisms?

◯Yes◉No◯Not Answered

D3-11-11. Herbal medicinal product?

◯Yes◉No◯Not Answered

D3-11-12. Homeopathic medicinal product?

◯Yes◉No◯Not Answered

D3-11-13. Another type of medicinal product?

◯Yes◉No◯Not Answered

D3-12. Specify the mode of action for the active substance in this medicinal product

Ibuprofen exerts an inhibitory effect on prostaglandin synthesis by inhibiting the activity of cyclo-oxygenase. In addition ibuprofen has an inhibitory effect on ADP (adenosine diphosphate) or collagen stimulated platelet aggregation.

D3-13. Is it an IMP to be used in a first-in-human clinical trial

◯Yes◉No◯Not Answered

D8. Placebo Information

D9. Site(s) where the qualified person certifies batch release

D9-1. IMPs and placebos for which no responsible site needs to be identified

If all the conditions below are met, then tick this box and select below the IMPs and placebos to which this applies☐

This section is used to identify IMPs and placebos which:

- has a MA in the EU and
- is sourced from the EU market and
- is used in the trial without modiciation (eg. Not over-encapsulated) and
- the packaging and labelling is carried out for local use only as per article 9.2 of the Directive 2005/28/EC (GCP Directive)

D9-2. Add Responsible Site

D9-2. Who is responsible in the Community for the certification of the finished IMPs?

D9-2-1/D9-2-2. As a manufacturer, importer or both?

Both

D9-2-3. Site Organisation Name

N/A

D9-2-4. Address

Street Address

N/A

Town/City

N/A

Post Code

N/A

Country

United Kingdom

D9-2-5. Manufacturer authorisation number

—

D9-2-5-1. If no authorisation, give the reasons

Field populated for verification purposes. Section D9 not applicable

D9-2. Site where the qualified person certifies batch release

Finished IMP

Description	Associate
PR1-Tablet	☐

Placebo

Pharmaceutical Form	Route of Administration	Associate
No items		

E. General Information on the Trial

E. Design of the Trial

Medical condition or disease under investigation

E1-1. Specify the medical condition(s) to be investigated:

Pain management for patients undergoing major gastrointestinal surgery

E1-1-1. Medical condition in easily understood language

Patients undergoing planned gut surgery

E1-1-2. Identify The Therapeutic Area

Diseases [C] - Symptoms and general pathology [C23]

E1-2. MedDRA information

MedDRA Search

Version	Term	Level	Classification Code	SOC	
22.1	Multimorbidity	LLT	10063914	General disorders and administration site conditions	

E1-3. Is any of the conditions being studied a rare disease?

◯Yes ◉No ◯Not Answered

E2. Objective of the trial

E2-1. Main objective of the trial

Is it feasible to deliver a randomised controlled trial of oral ibuprofen added to standard analgesia in patients undergoing major gut surgery, compared to usual analgesia without an NSAID? The findings from this trial will not be used in managing the patient's care. There are four main patient and hospital level objectives with the over-arching aim to provide a comprehensive portfolio of evidence to evaluate support for a definitive randomised trial:
a) To demonstrate willingness of patients to participate in the trial
b) To demonstrate whether relevant healthcare staff within participating hospitals are willing to randomise patients into the trial
c) To provide pilot data on the clinical effects of oral ibuprofen, in reducing pain after major elective gut surgery, compared to usual analgesia alone without a Non-Steroidal Anti- Inflammatory Drug (NSAID).
d) To provide safety data on the use of oral ibuprofen as an analgesic in patients undergoing major elective gut surgery.

E2-2. Secondary objectives of the trial

n/a

E2-3. Is there a sub-study?

◯Yes ◉No ◯Not Answered

E3. Please list the principal inclusion criteria (list the most important, max 5000 characters)

• Patients aged 18 years and over undergoing major elective gut surgery with bowel anastomosis

E4. Please list the principal exclusion criteria (list the most important, max 5000 characters)

• Inability or refusal to provide informed consent.
• Estimated glomerular filtration rate (eGFR) <45 ml/min.
• Known intolerance to NSAIDs that would preclude their use.
• Opioid dependence.
• Solid organ or bone marrow transplant.
• Previous enrolment in the PROTECT-AEGIS trial

E5-1. Primary end point(s) (max 5000 characters)

a. Patient outcome measures
• Number of doses of ibuprofen or other NSAID administered to each patient within 5 five days after surgery
• Overall Benefit of Analgesia Scores (OBAS) recorded daily for five days after surgery
• Total opioid dose (Oral Morphine Equivalents) within five days after surgery

• Numeric Rating Scale (NRS) pain scale on postoperative days one to five
• All complications graded by Clavien-Dindo within 30 days of surgery
• Mortality within 30 days of surgery
• Duration of hospital stay within 30 days of surgery
• Anastomotic leak graded by Clavien-Dindo within 30 days of surgery
• Acute kidney injury (KDIGO creatinine definition only criteria) within 30 days of surgery
• Gastro-intestinal bleed graded by Clavien-Dindo within 30 days of surgery
b. Hospital level feasibility outcome measures
• Number of eligible patients per year in each hospital.
• Number of eligible patients randomised per year in each hospital.
• Participating hospitals randomising at least one patient within the 12-month recruitment period.
• Number of consultant surgeons and anaesthetists in each hospital who support recruitment of the patients in their care in principle and the total number delivering care for elective colorectal surgery.

E5-1-1. Timepoint(s) of evaluation of this end point (max 800 characters)

As above.

E5-2. Secondary end point(s) (max 5000 characters)

N/a

E5-2-1. Timepoint(s) of evaluation of this end point (max 800 characters)

a/a

E6. Scope of the trial

E6-1. Diagnosis

○Yes◉No○Not Answered

E6-2. Prophylaxis

○Yes◉No○Not Answered

E6-3. Therapy

○Yes◉No○Not Answered

E6-4. Safety

○Yes◉No○Not Answered

E6-5. Efficacy

○Yes◉No○Not Answered

E6-6. Pharmacokinetic

○Yes◉No○Not Answered

E6-7. Pharmacodynamic

○Yes◉No○Not Answered

E6-8. Bioequivalence

○Yes◉No○Not Answered

E6-9. Dose Response

○Yes◉No○Not Answered

E6-10. Pharmacogenetic

○Yes◉No○Not Answered

E6-11. Pharmacogenomic

○Yes◉No○Not Answered

E6-12. Pharmacoeconomic

○Yes◉No○Not Answered

E6-13. Others

◉Yes○No○Not Answered

E6-13-1. Specify:

Feasibility

E7. Trial type and phase

E7-1. Human pharmacology (Phase I)

○Yes◉No○Not Answered

E7-2. Therapeutic exploratory (Phase II)

○Yes◉No○Not Answered

E7-3. Therapeutic confirmatory (Phase III)

○Yes◉No○Not Answered

E7-4. Therapeutic use (Phase IV)

◉Yes ○No ○Not Answered

E8. Design of the Trial

E8-1. Controlled?

◉Yes ○No ○Not Answered

Specify:

E8-1-1. Randomised

◉Yes ○No ○Not Answered

E8-1-2. Open

◉Yes ○No ○Not Answered

E8-1-3. Single blind

○Yes ◉No ○Not Answered

E8-1-4. Double blind

○Yes ◉No ○Not Answered

E8-1-5. Parallel group

○Yes ◉No ○Not Answered

E8-1-6. Cross over

○Yes ◉No ○Not Answered

E8-1-7. Other

◉Yes ○No ○Not Answered

E8-1-7-1. Specify the design of the trial

Standard care will consist of local protocolised analgesic measures without NSAIDs.

E8-2. If controlled, specify the comparator:

E8-2-1. Other medicinal product(s)

○Yes◉No○Not Answered

E8-2-2. Placebo

○Yes◉No○Not Answered

E8-2-3. Other

○Yes◉No○Not Answered

E8-2-4. Number of treatment arms in the trial

2

E8-3. Single site in the Member State concerned (see also section G)

○Yes◉No○Not Answered

E8-4. Multiple sites in the Member State concerned (see also section G)

◉Yes○No○Not Answered

E8-4-1. Number of sites anticipated in Member State concerned

9

E8-5. Multiple Member States

○Yes◉No○Not Answered

E8-6. Trial involving sites outside the EEA

E8-6-1. Trial being conducted both within and outside the EEA

○Yes◉No○Not Answered

E8-6-2. Trial conducted completely outside of the EEA

◉Yes○No○Not Answered

E8-6-3. Specify the countries in which trial sites are planned

Selected Countries
United Kingdom

E8-6-4. Specify the number of sites anticipated outside the EEA

9

E8-7. Trial having an independent data monitoring committee?

◉Yes ○No ○Not Answered

E8-8. Definition of the end of trial and justification in the case where it is not the last visit of the last subject undergoing the trial.
If it is the last visit of the last subject, please enter "LVLS". If it is not LVLS provide the definition.

Once 30-day follow-up is completed for all patients.

E8-9. Initial estimate of the duration of the trial (years, months, days)

E8-9-1. In the MS concerned

Years	Months	Days
2	11	29

E8-10. Proposed date of start of recruitment

E8-10-1. In the Member State concerned

01 March, 2025

E8-10-2. In any country

01 March, 2025

F. Population Of Trial Subjects

F1. Age Range

F1-1. Are the trial subjects under 18?

○Yes ◉No ○Not Answered

F1-2. Adult (18-64 years)

◉Yes ○No ○Not Answered

F1-2-1. Number of subjects for this age range:

200

F1-3. Elderly (greater than 65 years)

◉Yes ○No ○Not Answered

F1-3-1. Number of subjects for this age range:

200

F2. Gender

F2-1. Female

◉Yes ○No ○Not Answered

F2-2. Male

◉Yes ○No ○Not Answered

F3. Group of trial subjects

F3-1. Healthy volunteers

○Yes ◉No ○Not Answered

F3-2. Patients

◉Yes ○No ○Not Answered

F3-3. Specific vulnerable populations

○Yes ◉No ○Not Answered

F4. Planned number of subjects to be included

F4-1. In the member state

200

F5. Plans for treatment or care after a subject has ended his/her participation in the trial.
If it is different from the expected normal treatment, please specify:

none

G. Investigator Details

G1. National coordinating investigator (for a multicentre trial) or principal investigator (for a single centre trial)

National Coordinating Investigator

G1-1. Given Name	G1-2. Middle Name	G1-3. Family Name
Tom		Abbott

G1-4. Qualification (MD…)	G1-5. Institution Name	G1-5. Institution Department Name
MA PhD MRCP FRCA FHEA	Queen Mary University of London	William Harvey Research Institute

Address

Street Address
Royal London Hospital

Town/City
London

Post Code
E1 1FR

Country
United Kingdom

G1-5-5. Please indicate if site is:
Non-NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail
t.abbott@qmul.ac.uk

G2. What is the role of this investigator?
G2 Other principal investigator for a multicentre trial

G2-1. Given Name
Caroline

G2-2. Middle Name

G2-3. Family Name
Thomas

G2-4. Qualification (MD…)
MD

G2-5. Institution Name
Leeds Teaching Hospitals NHS Trust

G2-5. Institution Department Name

Address

Street Address
St James's University Hospital, Beckett Street

Town/City
Leeds

Post Code
LS9 7TF

Country
United Kingdom

G2-5-5. Please indicate if site is:
NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

caroline.thomas27@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Deena

G2-2. Middle Name

G2-3. Family Name

Harji

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

Manchester University NHS Foundation Trust

G2-5. Institution Department Name

Address

Street Address

Oxford Road

Town/City

Manchester

Post Code

M13 9WL

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

deena.harji@mft.nhs.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Shaman

G2-2. Middle Name

G2-3. Family Name

G2-4. Qualification (MD…)

G2-5. Institution Name

Jhanji	MD	The Royal Marsden NHS Trust

G2-5. Institution Department Name

Address

Street Address
Fulham Road

Town/City
London

Post Code
SW3 6JJ

Country
—

G2-5-5. Please indicate if site is:
NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail
shaman.jhanji@rmh.nhs.uk

G2. What is the role of this investigator?
G2 Other principal investigator for a multicentre trial

G2-1. Given Name
Shaun

G2-2. Middle Name

G2-3. Family Name
May

G2-4. Qualification (MD…)
MD

G2-5. Institution Name
Barts Health NHS Trust

G2-5. Institution Department Name

Address

Street Address
Royal London Hospital

Town/City
London

Post Code
E1 1FR

Country
United Kingdom

G2-5-5. Please indicate if site is:
NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

shaun.may@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Anil

G2-2. Middle Name

G2-3. Family Name

Hormis

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

The Rotherham NHS Foundation Trust

G2-5. Institution Department Name

Address

Street Address

Moorgate Road

Town/City

Rotherham

Post Code

S60 2UD

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

anilhormis@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Ashok

G2-2. Middle Name

G2-3. Family Name

Sundar

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

Croydon Health Services NHS Trust

G2-5. Institution Department Name

Address

Street Address

530 London Road

Town/City

Croydon

Post Code

CR7 7YE

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

sundar.ashok@nhs.net

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Patrice

G2-2. Middle Name

G2-3. Family Name

Forget

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

NHS Grampian

G2-5. Institution Department Name

Address

Street Address

Summerfield House 2 Eday Road

Town/City

Aberdeen

Post Code

AB15 6RE

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

forgetpatrice@yahoo.fr

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Aneel

G2-2. Middle Name

G2-3. Family Name

Bhangu

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

University Hospitals Birmingham NHS Foundation Trust

G2-5. Institution Department Name

Address

Street Address

Mindelsohn Way Edgbaston Birmingham,

Town/City

Birmingham

Post Code

B15 2GW

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

Fax Number

Country Dialing Prefix | Local Area Code | Phone Number

Extension

E-mail

a.a.bhangu@bham.ac.uk

G2. What is the role of this investigator?

G2 Other principal investigator for a multicentre trial

G2-1. Given Name

Rhona

G2-2. Middle Name

G2-3. Family Name

Sinclair

G2-4. Qualification (MD…)

MD

G2-5. Institution Name

Newcastle upon Tyne Hospitals NHS Foundation Trust

G2-5. Institution Department Name

Address

Street Address

Queen Victoria Road

Town/City

Newcastle

Post Code

NE1 4LP

Country

United Kingdom

G2-5-5. Please indicate if site is:

NHS

Telephone Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

Fax Number

Country Dialing Prefix

Local Area Code

Phone Number

Extension

E-mail

rhona.sinclair1@nhs.net

G3. Central technical facilities

G4. Trial Networks

G5. Sponsor's Subcontractor Facilities

H. Ethics Committee/National Competent Authority

H. National Competent Authority

H2-1. National Competent Authority name

UK - MHRA

H2.2. Address

Street Address

Town/City

Country

Post Code —

H2-3. Date of submission

18 November, 2024

H3. Authorisation/Opinion

H3-1/H3-2/H3-3. What is the status of the National Competent Authority's authorisation

Select..

H. Ethics Committee

H2-1. Ethics Committee name

London – City and East

H2.2. Address

Street Address

Town/City

Country

Post Code —

H2-3. Date of submission

—

H3. Authorisation/Opinion

H3-1/H3-2/H3-3. What is the status of the Ethics Committee's opinion?

Select..