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Information for Prospective Participants *UK Adult Immune Thrombocytopenia (ITP) Registry*

Invitation to participate in a research project

You are being invited to take part in a research study. Before you decide, it is important that you understand why this research is being conducted and what will be done. Please take time to read the following information carefully, to discuss it with us and others, and, finally, to decide whether or not you wish to take part. Feel free to ask us if there is anything unclear or on which you would like more information.

What is the UK adult ITP registry?

Immune (Idiopathic) thrombocytopenia (ITP) is an uncommon disease characterised by a low platelet count. While we know that this condition results from the rapid removal of platelets from the body by the immune system, we know very little regarding the underlying cause of platelet removal, despite many years treating ITP adult patients. We also do not have definitive answers to questions such as when treatment is needed and which treatments benefit which ITP patients.

Because ITP is a rare disease, individual hospitals will encounter only a small number of ITP patients which makes it difficult to observe patterns within ITP patients. Our aim, at the UK Adult ITP Registry, is to collect data from ITP patients from all over the country, in order to build a broad picture of ITP so that we can see emerging patterns. Collecting data from a large group of patients allows us to investigate subgroups of ITP patients. For example, it could be the case that people with a certain characteristic do not respond well to steroids, or a certain characteristic may be associated with more severe disease. Worldwide, there have been few studies on adult ITP. We hope that this registry will provide much of the information that we are currently lacking.

If you consent to be part of the Registry, your haematologist's team will collect relevant information from your medical records. In order to build a complete picture, we like to retrieve data from different sources, each of which will be explained below. ~~We ask for your permission to use each source of data separately. You are free to not consent to any or all of the sources below.~~

Hospital Records

With your permission, your haematologist's team will collect data from your hospital medical records. ~~This gives us the bulk of information we need including which treatments you've had and any previous bleeds.~~

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General Practitioner (GP) data

We also ask if you will allow ~~us your clinical team~~ to contact your GP and get a copy of your GP medical notes. ~~We often find that~~ GP records may have ~~some ITP-related~~ relevant information that can't be found in your hospital notes. ~~In particular, past treatments that you may have had at a different hospital. The information we request is the same as what we are looking for in your medical notes, but we ask to see the GP notes in case there is any extra information available.~~ You can ask your local team to see the GP Proforma (version 1.2) if you want to see an example of the information we extract. ~~You are free to decline access to your GP records.~~

NHS Data Linkage Service and Summary Care records

In addition, we may employ the NHS Data Linkage Service and Summary Care Records, which are used in clinical practice and research, to search for up-to-date information from certain electronic records held by the NHS and Office of National Statistics (ONS). ~~Again this is to find the same ITP-related information, but offers us another source for completeness of historical data.~~

By engaging these resources, we will obtain the best data to generate robust and reliable findings which we hope will assist future investigations into the cause of ITP and clinical decision making. All information will be stored in the registry database anonymously.

Data on pregnancy and the newborn

Dr Sue Robinson, Consultant Haematologist at Guy's and St Thomas' NHS Foundation Trust, has a specific interest in obstetric haematology and will collaboratively lead a study on pregnancy and newborn's health in ITP patients with the Chief Investigator Dr Vickie McDonald.

If you are eligible for this and willing to participate, you will be given a separate information sheet and consent form (UK ITP Pregnancy Registry Patient Information Sheet (2.0))

If you would like any further information in relation to this part of the study, please address your queries to:

Dr Susan Robinson (Sub-Investigator - ITP Registry – Pregnancy Section)
Guys & St Thomas NHS Foundation Trust,
Haematology Department
Great Maze Pond
London
SE1 9RT
Telephone: +44(0)2071883423
Email: Susan.Robinson@gstt.nhs.uk

Data management and protection

Barts Health NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from your medical notes in order to undertake this study and will act as the

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data controller for this study. This means that we are responsible for looking after your information and using it properly. Barts Health will keep identifiable information about you securely for 20 years from study closure in accordance with the Research Governance Framework and Trust Policy.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, the information kept in the adult ITP registry database itself is anonymised (you are not identifiable from this). In order to ensure we have a record of consent, we keep a list of participant names and their consent securely and separately from the registry database, within Barts Hospital secure internal network, with access only available to study personnel.

Data retrieval from your medical records will be done ~~(remotely)~~ ~~locally~~ at your hospital. Access to records at these sites will be extended to the chief investigator's team for monitoring and quality assurance purposes only. Importantly, all information collected about you will be kept strictly confidential. Any published data will be anonymised so that you cannot be identified from it. Your hospital site will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care. Individuals from Barts Health and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital site will pass these details to Barts Health along with the information collected from you and your medical notes. The only people in Barts Health who will have access to information that identifies you will be people who are ensuring data validity and may need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

~~Under strict control, the~~The UK ITP Registry may collaborate with fellow researchers outside of Queen Mary University of London in order to conduct some studies, especially those that require expertise and facilities not available at the University. If this collaboration is deemed necessary, the UK ITP Registry will enter into a data sharing agreement with these researchers where anonymised information may be shared for a defined period of time.

Within these constraints, study personnel will take all reasonable steps to protect your privacy.

Blood Samples for genetic analysis

~~We will investigate the role of genetics in ITP. In order to do this, we will- (anonymously) isolate, analyse and store your DNA and other components from the donated sample for use in medical research. Genes are made out of DNA. RNA is the version of the DNA code that the body uses to direct how proteins are made. We may determine the DNA/RNA code of the samples taken. This may include determining the sequence of all or part of your DNA code that relates to causes of ITP. We may measure a range of chemicals in these samples and may determine your genetic code.~~ ~~Genes are made out of DNA. RNA is the version of the DNA code that the body uses to direct how proteins are made. We may determine the DNA/RNA code of the samples taken. This may include determining the sequence of all or part of your DNA code.~~

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We also want to ~~will~~ investigate whether variations in genes may contribute to the differences seen in different patients with ITP. ~~the role of genetics in ITP.~~

In order to do this, we ask you if you are willing to donate 4-8 ml (1 to 2 teaspoons) of blood or other tissue to ~~use on one occasion.~~ Blood samples will be labelled with an anonymised code and sent to the Royal London Hospital. The genetic material will be extracted from and stored at Queen Mary University of London, allied to the Royal London Hospital, for future studies. Any blood not used for genetic material extraction will be discarded. You can be part of the ITP Registry without consenting to donate a blood sample and the collection of the blood sample do not have to take place at the same time as initial consent – it can take place some time later.

Blood samples for analysis of the immune system and platelets

As well as wanting to understand ~~if different genes~~ show genetics contribute to ITP, we want to know if certain cells, metabolites and proteins in ~~your blood~~ contribute to ITP. To do this, participants ~~from the Royal London Hospital~~ will be invited to take part in a sub-study looking at the cells, metabolites and proteins in your blood. In order to be part of it, you will be asked to donate four blood samples of 50ml (10 teaspoons) over a six month period. You will be free to decline further donations at any time. This is still a small amount of blood and you should not experience any side effects from donating this amount.

Blood samples will be sent by your haematology team to UK ITP Registry at the Royal London Hospital ~~where they will be stored.~~ Samples may be sent to other institutions for specialised tests ~~if the facilities are not available at the Royal London Hospital.~~ Samples will be sent to other centres anonymised and all results obtained will be coded in such a way that your identity will be unknown to researchers.

Can I know the results obtained from the study samples?

It is not planned to routinely feedback the results from genetic or other tests obtained from the donated samples. However, if the research does identify a cause of the rare disease in your family with your permission we would let your doctor and your clinical care team know. All research results that are identified will need to be confirmed in an accredited diagnostic laboratory before being used in the clinical management of you and your family members. We hope that the NHS will make reasonable efforts to introduce new tests for rare diseases. We will support these efforts where possible by sharing the results of our studies. Please be aware that the government has extended the genetic test insurance moratorium until 2019. This means there are restrictions which prevent providers from using genetic test results to deny people insurance cover until that set date.

Leaving the Registry

Of course, you do not have to join the study and may withdraw from it at any time. Please be assured that your decision not to take part will *not* affect your care in *any* way. If you would

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like to withdraw, please inform your local site staff or email the registry directly (uk-ityp.registryteam@nhs.net).

Should you decide to withdraw your consent to participate in this study the information you gave us before you left the study will still be used for research. Any remaining samples that can be linked to you will be destroyed at your request.

How may this research help?

Although this study is unlikely to have an immediate impact on you, it will likely benefit future patients by:

1. Helping us to find out what causes adult ITP.
2. Enabling us to predict whether a particular case of ITP will be mild or severe and the risk of developing other illnesses.
3. Resulting in a better understanding of which treatments to use in the future.
4. Helping us understand the outcome of pregnancy in ITP and which treatments to use in the future.

What will happen to the results of the study?

Results from the study will be published in peer-reviewed medical journals so that clinicians caring for adults ITP patients may be better able to manage their condition. Summary findings will additionally be published in *The Platelet*, the official newsletter of the ITP Support Association, and presented at the Annual ITP Support Association Convention. Study participants and collaborators will be kept informed of study progress through regular newsletters that will be available on our online study site, <https://www.qmul.ac.uk/itypregistry/>.

Who has reviewed the study?

The study has been carefully reviewed by our peers at the Institute of Cell and Molecular Science (ICMS) at Barts and The London School of Medicine and Dentistry, the Joint Research Office for Barts and the London NHS Trust and Barts and The London School of Medicine and Dentistry, and the London Central Research Ethics Committee. These reviews have all been favourable.

What happens if there is a problem?

While we do not expect you to suffer any harm as a result of your participation in the study, Barts Health NHS Trust has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of being part of this study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the study. These arrangements do not affect your right to pursue a claim through legal action.

Should you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of the study, please contact Queen Mary University of London on 020 7882 7250 to initiate the complaint procedure. You may also contact Patient Advisory Liaison Service (PALS) via telephone (020 7377 6335), minicom (020 7943 1350), or email (pals@bartshealth.nhs.uk). You may alternatively book a visit with a PALS representative by asking at any reception centre in your hospital.

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What can you do if you are worried or would like more information?

You will always be able to contact a member of the chief investigator's team to discuss your concerns and/or to get help (please see below). Should you wish to discuss concerns over participation with a neutral party, please feel free to contact the ITP Support Association

Though a financial sponsor of the molecular component of our study, the ITP Support Association remains first and foremost a patient support network and can be trusted in this regard as a provider of unbiased references.

Central Research Team

UK Registry Coordinating Team
Dr Vickie McDonald
(Consultant Haematologist and Chief Investigator)

Contact details

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+44 (0) 203 246 0473

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