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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 any material that is 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 removal of platelets 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 treatment benefits which ITP patients.

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 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 discover 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 linked to more severe disease. Worldwide, there have been very 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 ITP-related 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.

UK ITP REGISTRY PROSPECTIVE PATIENT OVERVIEW (3.2)

General Practitioner (GP) data

We also ask if you will allow us to contact your GP and get a copy of your GP medical notes. We often find that GP records may have some ITP-related 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 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 will 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 clinical decision making. All information will be stored in the registry database anonymously.

Data on pregnancy and 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 Prospective Patient Overview (1.0))

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 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 for 20 years from study closure in accordance with the Research Governance Framework and Trust Policy.

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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 internal network.

Data retrieval from your medical records will be done locally at your hospital. Access to records at these sites will be extended to the chief investigator's team but will be limited to 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. [NHS 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, and to oversee the quality of the study. Individuals from Barts Health and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS 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 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 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

ITP is a variable disease. We don't understand why the disease can affect people differently, nor do we understand why some people respond to certain treatments whilst others do not. We want to investigate whether variations in genes that make up our immune system may contribute to the differences seen 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 on one occasion. Blood samples will be labelled with an anonymised code and sent to the Royal London Hospital. We will extract the DNA from this blood and store the DNA at the Royal London Hospital for future studies. Any blood not used for DNA extraction will be discarded. You can be part of the ITP Registry without consenting to donate a blood sample.

As well as wanting to understand if different genes contribute to ITP, we want to know if certain cells 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 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.

What will happen to my samples?

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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.

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 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, www.ukitpregistry.com.

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

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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.

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 Mrs Shirley Watson, Chief Administrator of the ITP Support Association via phone (012-3437-6559); she will be happy to put you in contact with a clinical ITP expert not directly involved with our study.

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)

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