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Information for Haematologists

UK Adult Immune Thrombocytopenic Purpura (ITP) Registry

Invitation to collaborate on a research project

You are being invited to collaborate on a multi-centre study of adult immune (idiopathic) thrombocytopenic purpura (ITP) in the United Kingdom. Please take time to read the following information carefully, before deciding whether or not you wish to take part. Feel free to ask us if any material is unclear or you would like more information.

What is the UK adult ITP registry?

As you are aware, ITP is a relatively rare autoimmune disorder characterised by low platelet count. While we know that this condition results from the removal of antibody coated platelets by the reticuloendothelial system, we know very little regarding the underlying cause(s) of antibody attachment to platelets and, despite many years treating ITP adult patients, do not have sufficiently evidence-based answers to such questions as when treatment is needed and which treatment may be best for a particular patient.

Individual hospitals will encounter only a small number of ITP patients. A disease registry will allow us to assemble a sufficient number of patients to obtain generalisable results regarding the severity of ITP a patient will have, his/her response to available treatments, and his/her susceptibility to co-morbid disease. Worldwide, there have been very few epidemiological studies on adult ITP; we hope that this registry will provide much of the information that we are currently lacking.

As part of our planned ten-year investigation, we will regularly extract ITP-related information from the medical records of study participants. We will also engage the Data Linkage Services provided by the Health and Social Care Information Centre (HSCIC). This service is provided by the NHS to researchers who wish to trace their participants for study-related data on certain datasets that are securely managed by the NHS and the Office of National Statistics. This will ensure that our cohort remains as complete and up-to-date as possible. We will also use the Summary Care Records (which is in upload process nationally) and will contact general practitioners for study-related information for the same reasons above. We recognized that general practitioners are very important to our study as they are more up-to-date on certain study-related information that we ought to capture. Any information that we receive from the general practitioners will also be forwarded to your team.

The information permissible for extraction has been explicitly codified and is documented within the initial and update information sheets available on our study website, www.ukitpregistry.com. Additionally, we will collect a small blood sample (15 mL) from patients during a routinely scheduled venepuncture (or a saliva sample [Oragene® kit]) at the time of registration. Genetic material (DNA & RNA [where possible]) from this sample will be extracted and used for the molecular component of the study described later.

Eligible patients will be mailed a comprehensive, lay overview of the study (**UKITP Prospective Participant Overview 3.1**), which will contain means through which to contact both the chief investigator and his team with pre or post-enrolment questions or concerns.

Included with this paperwork will be two informed consent agreements concerning the study and subsequent tissue storage respectively, returnable to the study coordinator via a pre-paid, self-addressed envelope.

Data protection

The collection of information from medical records at The Royal London Hospital and the aforementioned NHS resources will be performed by the chief investigator's team. For participants at all other centres, the data retrieval process will be conducted by a member of the local clinical care team. 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 will be kept strictly confidential. Any published data will be anonymised so that participants cannot be identified from it. Annually during the study, fully-anonymised data will be shared with medical researchers at GlaxoSmithKline Research Ltd. and the Paediatric & Adult Intercontinental Registry on Chronic Idiopathic Thrombocytopenic Purpura (PARC-ITP) Study in Basel, Switzerland. These partnerships will enhance resources with which to investigate the natural progression, causes, and treatment of adult ITP while strengthening analysis of the study's findings. The information submitted to these two organisations will contain no personally-identifiable material, and all planned analyses utilising it will require favourable review from a research oversight body.

Molecular investigation of adult ITP

The molecular investigation of adult ITP will comprise a scientific study of single nucleotide polymorphisms (SNPs) within cytokine genes and the expression pattern of these genes. We would like to investigate whether certain SNPs or gene expression patterns are associated with observed differences in ITP severity and treatment effectiveness. We would additionally very much like to compare the activity of patients' cytokine genes with activity patterns found among healthy individuals with the hope that this comparison may yield aetiological hypotheses for further testing.

How may this research help?
Although this study will likely not have an immediate impact on individual participants, it will likely benefit future patients by

1. helping us to gauge the likely progression of ITP among individuals.

2. enabling us to predict the likely effectiveness of treatments among individuals.

3. yielding aetiological hypotheses for investigation in future studies.

What are we asking from you?

If you agree to collaborate on this study, we will call upon you

(a) to identify ***all*** adult ITP patients visiting your outpatient haematology clinic, to provide these patients with a brief overview of the objectives and protocol of the study, and to request permission to forward their name and address to the study coordinator.

(b) to identify a member of the clinical care team who will complete the registration and annual information sheets for each participant using information abstracted from hospital medical records.

(c) to identify a member of the clinical care team who will collect an extra 15 mL of blood from participants during a routinely schedule venepuncture (or a saliva sample [Oragene® kit]) at the time of registration.

(d) to identify a member of staff who will be responsible for transmitting information to the chief investigator's team and who will serve as the chief liaison for the centre.

While all obtained results will be coded in such a way that patients' identities will be unknown to researchers, we will ask that you provide patient demographic information on the initial information sheet in order to provide the study coordinator with an accurate means of follow-up. Upon receipt of this document, a unique reference number will be allocated to the study participant. This number will be shared with you alone and will be used for all subsequent data collection, storage, and transfer, including the semi-anonymisation of participant blood samples.
Importantly, patients do not have to join the study and may withdraw from it at any time. Please assure them that their decision not to take part will ***not*** affect their care in ***any*** way.

Duration of the study

The study will last a total of 11 years, concluding in 2018.

What will happen to the results of the study?

Results from the study will be periodically published in peer-reviewed medical journals in which acknowledgement of the contribution of collaborating study centres will be made. 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 a bi-monthly study newsletter 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, GlaxoSmithKline (GSK) Worldwide Epidemiology, the Joint Research Office for Barts and the London NHS Trust and Barts and The London School of Medicine and Dentistry, and the London Research Ethics Committee. These reviews have all been favourable.

What happens if there is a problem?

There are no hazards arising from this research apart from normal risks resulting from routine care. Thus, we do not expect patients to suffer any harm as a result of their participation in the study. However, it is important to note that no special compensation arrangement exists should harm occur. Were patients harmed as a result of someone's negligence, they may have grounds for legal action but may have to pay their own legal costs.

Should they wish to complain or have any concerns about any aspect of the way they have been approached or treated during the course of the study, normal National Health Service complaint mechanisms will be available to them. In such instances, we would ask that patients please contact Patient Advisory Liason Service (PALS) via telephone (020 7377 6335), minicom (020 7943 1350), or email (pals@bartsandthelondon.nhs.uk). They may alternatively visit with a PALS representative by asking at any reception centre in the hospital.

What do you do if you would like to take part in this collaboration or would like more information?

You will always be able to contact a member of the chief investigator's team to discuss your concerns. If you would like to take part in this collaboration upon consideration of the aforementioned information, we would ask that you please contact the chief investigator and or a member of his team via phone or email as shown below.

	Chief Investigator /Consultant Haematologist	**Lead Epidemiologist**	**Data Manager & Study Coordinator**
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