The UK Adult ITP Registry

Haroon Miah, Data Manager

October 2018
Background

• Based in The Royal London Hospital

• Active since 2007

• Under the leadership of Dr Drew Provan

• Dr Daniel Hart

• Current CI is Dr Vickie McDonald (July 2018)
Current Team

[Images of the current team members]
Aims of the registry

• Understand ITP in the UK, how it is treated, outcomes after treatments and clues to causes throughout all stages of adult life.

• Focusing on patients with Primary ITP.

• Collecting clinical information and DNA (if patients give consent).

• Are there possible genetic associations with primary ITP and response to treatments?

• As of September 2018 – a sub-study to investigate primary ITP in Pregnancy added.
Methodology

8.1 Study Scheme Diagram

UKITP REGISTRY STUDY PROTOCOL 2.3

Participant Written Informed Consent.

Patient added to Participants Log to give them a Registration Identification Code (RIC).

Participant consented to give blood sample?

no

Participant consented to retrieve GP notes?

yes

3-5ml whole blood sample in EDTA is taken and sent to The Registry.

Participant consented to retrieve GP notes?

yes

no

GP contacted and asked to send copy of participant’s notes.

Follow up data entered on ITP Registry database at least annually.

Participant information extracted from hospital records entered on ITP Registry database

Participant information extracted from hospital records and GP notes entered on ITP Registry database

Participant Information extracted from hospital records entered on ITP Registry database
Registry Database

- Moved to a new database – REDCap (2017)
- Secure online database that is encrypted
- Data entry can take place from any participating site
- REDCap is used by over 3000 institutions in 128 countries
- Simplified data entry and easier to use
Welcome to the REDCap service provided by Queen Mary University of London

Published research should cite REDCap as follows:

Study data were collected and managed using REDCap electronic data capture tools hosted at Queen Mary University of London [1]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.


Please log in with your user name and password. If you are having trouble logging in, please contact Research IT Support.
The UK ITP Registry

**Add / Edit Records**

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

**Total records:** 3,204

**Choose an existing Registry Identification Code (RIC)**

Arm 1: UK ITP Registry — select record

**Enter a new or existing Registry Identification Code (RIC)**

Arm 1: UK ITP Registry

**Data Search**

**Choose a field to search**
(excludes multiple choice fields)

All fields

**Search query**

Begin typing to search the project data, then click an item in the list to navigate to that record.
The UK ITP Registry

**Record Home Page**

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the **Define My Events** page.

Choose action for record

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**Registry Identification Code (RIC)** XTS10316

Arm 1: UK ITP Registry — Royal London Hospital

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>UK ITP Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Details</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Date of Follow Ups</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Clinician Information</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Anthropometric and Lifestyle Data</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Bleeding events</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Splenectomy</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>ITP Treatments</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Supportive Therapies</td>
<td>![Status Icon]</td>
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<tr>
<td>Comorbidities</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Family History</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Biochemical Tests At Diagnosis</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Haematological Fields At Diagnosis</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Immunological Fields At Itp Diagnosis</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Coagulation Fields At Itp Diagnosis</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Full Blood Counts (Hbs, Neutrophils, Plts)</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Platelet Counts File Upload Function</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Bone Marrow Biopsy, DAT, Indium Scanning</td>
<td>![Status Icon]</td>
</tr>
<tr>
<td>Comments</td>
<td>![Status Icon]</td>
</tr>
</tbody>
</table>
Recruitment

- 3252 patients recruited to date.
- Top 10 recruiting sites by patient numbers:

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Number consented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 THE ROYAL LONDON HOSPITAL</td>
<td>281</td>
</tr>
<tr>
<td>2 UNIVERSITY COLLEGE HOSPITAL</td>
<td>150</td>
</tr>
<tr>
<td>3 SUNDERLAND ROYAL HOSPITAL</td>
<td>123</td>
</tr>
<tr>
<td>4 THE ROYAL VICTORIA INFIRMARY, NEWCASTLE</td>
<td>120</td>
</tr>
<tr>
<td>5 HAMMERSMITH HOSPITAL, IMPERIAL</td>
<td>119</td>
</tr>
<tr>
<td>6 CASTLE HILL HOSPITAL</td>
<td>110</td>
</tr>
<tr>
<td>7 KENT &amp; CANTERBURY HOSPITAL</td>
<td>98</td>
</tr>
<tr>
<td>8 NORTHWICK PARK HOSPITAL</td>
<td>94</td>
</tr>
<tr>
<td>9 QUEEN ALEXANDRA HOSPITAL</td>
<td>77</td>
</tr>
<tr>
<td>10 GLASGOW ROYAL INFIRMARY</td>
<td>71</td>
</tr>
</tbody>
</table>
Importance of the Registry

• ITP is rare and ability to collect data on as many cases as possible means we can understand it better.

• Provide evidence based answers on when treatment is needed and what is the best treatment for a particular patient.

• Information on responses to available treatments

• Susceptibility to co-morbid disease.

• Better to have standard information when trying to perform research
Presentations

• Talks and Poster presentations of our work at meetings:
  
  – National:
    • British Society for Haematology meetings: 2017, 2018
  
  – International
    • European Haematology Association: 2017, 2018
    • American Society for Haematology: 2017

• Topics
  
  – Rituximab treatment; effectiveness of low dose vs high dose
  
  – Thrombosis rates
  
  – Outcomes using treatments such as romiplostim (Nplate) and eltrombopag (Revolade)
Publications


- Case report of eltrombopag in a pregnant patient with ITP. KLM White, L Bowles, D Provan, L Taylor, A Newland, BSH, 2017

- Comparison of the effects of the TPO receptor agonist, Romiplostim, in patients with ITP < 1yr versus > 1yr. DJ Kuter, AC Newland, BH Chong, F Rodegheiro, MT Romero, I Pabinger, Y Chen, B Metha, M Eisen ASH 2017; BLOOD 2017, 130, 1055
Our website

http://ukitpregistry.com

Thanks to Drew Provan, our technology guru!
Hello and welcome to the latest issue of the UK Adult ITP Registry newsletter! Thank you to everyone for their ongoing support and working with the registry.

Study Updates

Pregnancy arm of UK ITP Registry
The latest version of the study protocol will now include consenting participants with primary ITP in pregnancy (previously this was an exclusion). Pregnant women diagnosed with primary ITP prior to or during their current pregnancy will be consented for the sub-study. It is important to note that this is not a separate study to the main ITP registry and will not require separate R&D approval. Patients who meet the inclusion criteria for the pregnancy arm of the study will have to complete 2 consent forms; one for the main adult ITP registry and the other for the pregnancy registry.

Registry Database
The Registry REDCap database has been successfully updated and is live!

You should have received an email giving you access to the project on REDCap. If you have not received this email or you cannot access the database, please get in touch.

One of the major changes was to incorporate the pregnancy arm of the study, as mentioned above. Please ensure to update your participant logs to include a new column titled ‘Pregnancy Registry Consent Date’. This is only for participants that consent for the pregnancy arm of the study.

We have updated the user guides and pro formas to reflect the latest version of the database—these can be found in the ‘File Repository’ on REDCap.

For any further information or clarifications, please do not hesitate to contact us.

Reminders

Local approvals for latest substantial protocol amendment:
The HRA notification email was sent to all sites on 06/05/2018 detailing the REC and HRA approvals for the latest substantial protocol amendment along with the document pack.

The new version of the protocol, version 2.3 dated 16/05/2018, can now be implemented (as of 10/09/2018). If you haven’t done so already, please send through confirmation of your local R&D approvals.

Please send through the localised versions of your patient information sheets and informed consent forms to the registry team.

This is also a great opportunity to send through updated delegation logs and CVs (2 page versions, signed and dated) and GCP certificates.
Funding

• Fantastic support from the patient support association: THANK YOU!

• Additional Grants from (2010 – 2018)
  – Barts Charity
  – Novartis
  – Amgen
  – Rigel
THANK YOU TO ALL THE PATIENTS

WE COULDN’T DO THIS WITHOUT YOU