The United Kingdom Thrombotic Thrombocytopenic Purpura Registry (TTP Registry)

Why are we doing the study?

Thrombotic Thrombocytopenic Purpura or TTP for short, is a rare disorder and we are collecting information from patients admitted with TTP throughout the UK. The study is a Registry of TTP admission in the UK. Therefore, with all of the UK involved, we hope to gain a better understanding of TTP.

Why have I been chosen and what does the UK TTP Registry involve?

The majority of TTP cases are caused by reduced levels of an enzyme called ADAMTS13. As part of standard clinical care a number of blood samples are taken when a patient is admitted for a suspected TTP episode, and one of these samples is used to measure levels of ADMATS13. You will be asked during the consent process if you will allow some of this sample to be sent and stored at UCLH. This will allow a large number of samples to be collected so we can analyse them as a group/subgroup to help further research, to understand TTP and related thrombotic microangiopathies.

When you have been discharged from hospital and are in remission your doctor will take another sample to measure ADAMTS13 as part of standard care, and you will be asked if you would like to take part in the UK TTP Registry. This is to allow information, such as the symptoms you had on admission, treatment and complications during your hospital stay to be recorded in the UK TTP Registry. Other data that we require for the registry are your routine blood test results from your stay in hospital and your ADAMTS13 results. As part of this project, we will also ask you for an extra blood sample, called an EDTA sample, from which DNA will be removed, this DNA will then be stored frozen at the Haemostasis Research Unit at UCLH. The DNA analysis results from all the patients participating in The UK TTP Registry will be looked at together, to see if any of the genes identified have any relevance to the risk of presenting with TTP, the potential responses to treatment or the risk of relapse.

Congenital TTP

Since the UK TTP registry started, we have identified a number of congenital TTP cases. Many are in pregnant women who have had no previous history. Congenital TTP is very rare, only accounting for a small percentage of all TTP cases. It is confirmed by genetic testing. Following the initial presentation, patients are consented for the UK TTP registry-acute TTP as often the diagnosis takes longer to confirm. However, treatments used and follow up, including well being questionnaires and brain assessment will be undertaken each year. The treatments are slightly different to the immune type of TTP and involve replacing the missing enzyme and no immune therapies. As congenital TTP is very rare, it is very important for researchers to understand how often replacement treatment is given, what time of replacement treatment and what effect this is having on any symptoms and blood counts.

Follow up information

All patients will now have longer term information collected, including there blood counts, symptoms, any new conditions that have been diagnosed, treatments and ADAMTS 13 levels. This information will be captured yearly and collected as part of the registry. Included will be a brain assessment, which is a series of questions and a patient health questionnaire. This

information is important for researchers to understand the potential impact of TTP in the longer term and over time. This will be collected yearly.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or decision not to take part, will not affect the standard of care you receive. If you have any concerns about participating in research the Patient Advisory and Liaison Service (PALS) will provide you with independent information and advice at your hospital.

What are the benefits of taking part in this research?

We hope to understand more about TTP. As it is a rare disorder, the more sites in the UK treating TTP that are involved, more data can be collected. The information from this study may help us to increase our understanding and improve future treatment for patients with TTP.

Data storage and review

All patients who agree to participate in the study must agree to their hospital notes and clinical study data being reviewed by researchers conducting the research, UCLH personnel for purposes of monitoring and auditing and Regulatory Agencies for purposes of external inspections. You will be allocated a specific study identification number when you are enrolled in this trial and this will be used to identify you throughout your participation. Personal information will be retained in a confidential manner and will not be available to external personnel.

Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called Research Ethics Committee (REC) to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable ethics opinion by Lewisham Research Ethics Committee (now known as South East London REC 5).

Thank you for taking the time to read this information sheet.