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The low platelet blood study

Submission date	Recruitment status	[ ] Prospectively registered
05/01/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/01/2017	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/01/2017	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Platelets are the component of blood which helps the blood to clot. A low platelet count can cause bleeding and bruising which can sometimes be serious. There are many different causes and treatments depend on the cause. It is not always easy for doctors to diagnose the cause and often many investigations are needed including uncomfortable bone marrow biopsy tests. In addition, even when the cause is known, different treatments may be tried before finding one that works. Some of the treatments used may have side effects and it would be helpful to develop blood tests that would predict which medicines will make which patients better. This would help treatment to be individualised, speeding up the time to get better and avoiding side effects of treatments that don't work. This study aims to develop new laboratory test to help with the diagnosis, identification of how the disease is working and prediction of treatment response in patients with low platelet counts.

Who can participate?
Patients aged 16 years and over who have a low platelet count and are in need of treatment.

What does the study involve?
During routine hospital appointments, patients with low platelet counts are asked if they are happy to provide an extra sample of blood when having routine blood tests. The blood samples are then sent to different laboratory studies so that new tests can be developed to help with the diagnosis, identification of how the disease is working and prediction of treatment response in patients with low platelet counts.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Bristol Haematology and Oncology Centre (UK)

When is the study starting and how long is it expected to run for?
January 2015 to March 2018

Who is funding the study?
Above and Beyond (UK)

Who is the main contact?
Dr Charlotte Bradbury
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
The development of laboratory assays for patients with low platelet counts to help predict treatment responses

Study objectives
The aim of this study is to develop new laboratory tests to assist with diagnosis, identification of disease mechanism and prediction of treatment response in patients with low circulating platelet counts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Brighton and Sussex NRES Committee, 30/11/2015, ref: 15/LO/2088

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Thrombocytopenia

Interventions
There will be no additional hospital appointments or venepunctures done specifically for this research. During a routine hospital appointment, each participant will be given patient information and the opportunity to ask questions. They will then be asked to given written consent. Following consent, when they are having other bloods done we will take extra blood samples for research (maximum of 50ml). The consent procedure is estimated to take 30 mins and is done by the Consultant in charge of their haematology condition. The samples will be anonymised and sent to different laboratory's in Bristol for different assays: NHS BT Filton for antibody assays, North Bristol haematology laboratory for lymphocyte subsets, UH Bristol haematology laboratory for platelet counting and ROTEM if done and University of Bristol research laboratory's for short term lymphocyte culture experiments. DNA may also be stored in a secure -70 freezer on level 8 BRI.

Patients may be asked to give further samples (maximum of 3 times per year).

Patients will receive standard treatments according to their condition and treatment responses (bleeding episodes, platelet count data, side effects) will be anonymised and recorded on a secure database. The results of laboratory assays will be correlated with clinical data over a minimum of 12 months.

Intervention Type

Primary outcome measure
Candidate biomarkers of clinical response are assessed by evaluating the correlation of laboratory assay results to clinical response data (bleeding and platelet count data over at least 12 months, the latter will be collected from routine blood tests done on patients according to clinical need).

Secondary outcome measures
Positive and negative predictive value of some assays to specific causes of low platelet count and discrepancy of results from different types of assay used to measure low platelet counts.

Overall study start date
07/03/2016

Completion date
05/01/2026

Eligibility

Key inclusion criteria
1. Age range >16 years old
2. Male and female
3. Low platelet count AND need for treatment
4. Hb>100g/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Hb<100g/L
2. Patients unable to consent (e.g. due to mental incapacity)

Date of first enrolment
07/03/2016

Date of final enrolment
05/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Haematology and Oncology Centre
University Hospital Bristol
Horfield Road
Bristol
United Kingdom
BS2 8ED

Sponsor information

Organisation
University of Bristol

Sponsor details
Tyndall Avenue
Bristol
England
United Kingdom
BS81TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
Above and Beyond

Results and Publications

Publication and dissemination plan

Planned presentation of the research findings at international meetings and publish them in high-impact peer reviewed journals. It is expected that some interim results be ready within 3 years by 2020. In addition, a plain English summary of the research findings will be published in “the platelet” a monthly magazine from the ITP support association (a patient and public group).

Intention to publish date
05/01/2027

Individual participant data (IPD) sharing plan
This study will generate numerous sets of complex data for different elements of this study. The remit of the study is broad, and aims to generate pilot data to be validated prospectively in future clinical trials. Due to the complexity of the data generated, at present we cannot guarantee we will be able to make available participant level data but we do plan to generate a plain English summary of the main research findings when available. The anonymised data will be stored securely.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No