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VWF platelet study: a pilot study of von Willebrand factor for moderate or severe thrombocytopenia

Submission date
13/02/2015

Recruitment status
No longer recruiting

Registration date
24/03/2015

Overall study status
Completed

Last Edited
21/12/2020

Condition category
Haematological Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Platelets are blood cells that help the blood clot. They are an important first line of defence against bleeding. Platelet numbers may be low if a person doesn't make enough platelets or if their platelets are broken down too quickly once they are made. People with low platelet counts are more vulnerable to bleeding. If they undergo surgery or start to bleed, a transfusion of platelets taken from blood donors is often needed to stop the bleeding. Platelet transfusions have a number of disadvantages: supplies are limited, they are expensive, there can be side effects such as bacterial infections and allergic reactions, and some patients do not benefit. Von Willebrand factor (vWF) naturally occurs in the body and causes platelets to stick to sites of injury to stop bleeding. Initial tests have been performed on the blood of volunteers with normal platelet counts. Their blood was treated to lower the platelet count. Adding vWF to the blood samples considerably improved the way their platelets worked. This study aims to investigate in the laboratory if adding vWF to blood from people with low platelet counts could improve the way the platelets work so that platelet transfusions are no longer needed.

Who can participate?
Patients aged 18 or over with low platelet counts (e.g., immune thrombocytopenic purpura or a bone marrow failure syndrome such as myelodysplastic syndrome).

What does the study involve?
Patients with low platelet counts will be asked if they will give extra blood for a laboratory investigation when they next have blood taken. The volume of extra blood is equivalent to three teaspoons and will be rapidly remade by the body. Patients will be asked questions about medications and recent food that they have eaten, as these can cause changes in the test results. The blood samples will be analysed in the laboratory. Firstly the patient's platelet count will be rechecked. If there are more than 50 billion platelets per litre, it will not be analysed further. If there are less than 50 billion per litre then further tests will be performed to see how well the platelets are working. vWF will then be added to the blood samples and the tests will be repeated.

What are the possible benefits and risks of participating?
There are no direct benefits for patients who agree to take part in the study. We hope that this study will allow us to identify new ways to treat bleeding for patients with low platelet counts in the future. The risk of any complication from extra blood being taken is minimal.

Where is the study run from?
Churchill Hospital (UK).

When is the study starting and how long is it expected to run for?
From April to September 2015.

Who is funding the study?
Investigator initiated and funded (UK).

Who is the main contact?
Dr Michael Desborough

Contact information

Type(s)
Public

Contact name
Dr Michael Desborough

ORCID ID
http://orcid.org/0000-0002-1951-5616

Contact details
NHS Blood and Transplant
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

VWF platelet study: a pilot observational study of von Willebrand factor for moderate or severe thrombocytopenia

Acronym
vWF Platelet Study

Study objectives
To determine whether the addition of intermediate purity factor VIII (a source of von Willebrand factor) to the donated blood of thrombocytopenic patients improves their platelet function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Haydock, 11/02/2015, ref: 15/NW/0138

Study design
Observational single-centre trial

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Immune thrombocytopenic purpura or thrombocytopenia due to bone marrow failure

Interventions
Platelet function will be tested on blood donated by patients. These tests will be repeated after addition of intermediate purity factor VIII.

Intervention Type
Other

Primary outcome measure
Normalisation of platelet function, measured with a platelet function analyser 200 adenosine diphosphate/collagen cartridge after addition of intermediate purity factor VIII

Secondary outcome measures

1. Normalisation of platelet function, measured with microfluidics using collagen as an agonist under arterial shear force conditions after addition of intermediate purity factor VIII
2. Normalisation of platelet function, measured with a platelet function analyser 200 P2Y2 cartridge after addition of intermediate purity factor VIII

Overall study start date
01/04/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Confirmed diagnosis of immune thrombocytopenic purpura or a bone marrow failure syndrome such as myelodysplastic syndrome
3. Platelet count less than 50x10^9/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Any inherited platelet disorder or von Willebrand disease
2. Use of an antiplatelet agent (e.g. aspirin or clopidogrel) in the 7 days before blood sampling

Date of first enrolment
01/04/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
NHS Blood and Transplant

Sponsor details
R&D Administration
NHS Blood and Transplant
500 North Bristol Park
Bristol
England
United Kingdom
BS34 7QH

Sponsor type
Hospital/treatment centre

Website
http://www.nhsbt.nhs.uk

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

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