

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/12/2020	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 $50 \times 10^9/l$

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