

Global assays for haemophilia

Submission date 19/06/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/04/2018	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Haemophilia A is an inherited clotting disorder primarily affecting males. It is caused by having a low level of a clotting factor called factor VIII (FVIII). Haemophilia B is also caused by low levels of a clotting factor and this is caused by having a reduction in factor IX (FIX). Haemophilia (both A and B) increases the risk of bleeding, particularly in the joints and muscles. Patients with factor levels of <1% are defined as having severe haemophilia, patients with levels between 1-4% are said to suffer from moderate disease and patients with levels of 5% or greater are said to suffer from mild Haemophilia defined as mild disease. Patients with severe haemophilia are at greatest risk of spontaneous bleeds (bleeding for no reason) and require regular treatment with intravenous infusions of clotting factors to prevent bleeding. At the moment monitoring of treatment and predicting the likely risk of bleeding for patients with haemophilia is determined using a standard clotting test, where the factor VIII or factor IX is measured. But not all patients with similar clotting factor levels (both baseline levels and post-treatment levels) have the same tendency for bleeding. Newer clotting tests: known as 'global haemostasis assays' may be better at telling doctors whether a patient will be more or less likely to bleed after treatment. These tests look at lots of different, interacting parts of the clotting system. This study will tests two global clotting tests: thrombin generation and a viscoelastic test called rotational thromboelastometry (ROTEM). These tests will be evaluated and compared to standard tests, both to see if these tests are accurate and also to see if they correlate better with patients' bleeding risks.

Who can participate?

Adult men (aged at least 18) diagnosed with haemophilia.

What does the study involve?

Participants are asked to provide one or two additional aliquots of blood (5.4 ml citrated blood) for this study whilst undergoing routine clinical assessment. No additional blood draws are requested over and above the samples that are taken at the time of the patients' routine blood draws. All patients with haemophilia are routinely assessed at each clinic appointment by means of at least one blood sample; a 'baseline' blood sample is taken for testing either factor VIII or factor IX levels. Patients who require prophylactic treatment (regular infusions) routinely have two blood samples taken in clinic: a trough level and a post-infusion level. A trough sample is a blood test taken just before the next dose of clotting factor is required and gives an estimate of how much of the factor remains in a patient's blood stream. The trough level can be used to

guide ongoing therapy. The post-infusion level provides information about how much the factor level rises in the blood stream after an injection.

What are the possible benefits and risks of participating?

There are no risks and no immediate benefits from taking part in this study.

Where is the study run from?

Oxford Haemophilia & Thrombosis Centre (UK)

When is the study starting and how long is it expected to run for?

October 2015 to March 2016

Who is funding the study?

Blood Coagulation and Research Fund, Oxford Haemophilia and Thrombosis Centre (OHTC) (UK)

Who is the main contact?

Dr Nicola Curry

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.0

Study information

Scientific Title

Global haemostasis assays: their use in patients with haemophilia

Study objectives

This is an observational study evaluating the utility of global haemostasis assays (i.e. thrombin generation (TGT) and thromboelastometry (ROTEM)) in assessing haemostatic ability in haemophilia patients. the primary objectives are to: find a normal range for TGT and ROTEM for both haemophilia and control subjects and to determine the reproducibility of these assays. Secondary objectives are: to correlate clinical outcomes in patients with haemophilia with TGT and ROTEM values and to compare these results with standard laboratory factor assay measurements.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central - Oxford C, 15/07/2015, ref: 15/SC/0316

Study design

Single-centre observational study

Primary study design

Observational

Secondary study design

This is a laboratory study evaluating global assays of haemostasis

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

This study is evaluating newer global blood clotting tests and their use and reproducibility in patients with haemophilia A and haemophilia B.

Interventions

Participants will be asked to provide one or two additional aliquots of blood (5.4 ml citrated blood) for this study whilst undergoing routine clinical assessment. No additional blood draws will be requested over and above the samples that are taken at the time of the patients' routine blood draws.

All patients with haemophilia are routinely assessed at each clinic appointment by means of at least one blood sample; a 'baseline' blood sample is taken for testing either factor VIII or factor IX levels.

Patients who require prophylactic treatment (regular infusions) routinely have two blood samples taken in clinic: a trough level and a post-infusion level. A trough sample is a blood test taken just before the next dose of clotting factor is required and gives an estimate of how much of the factor remains in a patient's blood stream. The trough level can be used to guide ongoing therapy. The post-infusion level provides information about how much the factor level rises in the blood stream after an injection.

Intervention Type

Other

Primary outcome measure

The primary outcome is to find a normal range for thrombin generation and ROTEM measures in patients with haemophilia as measured by evaluating a blood sample at time 0 hours. The blood will be tested for thrombin generation and for whole blood viscoelastometric measures which are both global measures of coagulation.

Secondary outcome measures

Secondary outcome will be to correlate the laboratory tests with clinical outcome. Thrombin generation measures and ROTEM measures will be compared at time 0 hours and correlated with the number of joint bleeds that a patient has as measured using an annualised bleeding rate.

Overall study start date

01/10/2015

Completion date

31/03/2016

Eligibility

Key inclusion criteria

1. Participant is willing and able to give informed consent for participation in the study
2. Male, aged 18 years or above
3. Diagnosed with haemophilia A or B

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

50

Key exclusion criteria

Concomitant use of pro-haemostatic agents such as tranexamic acid or anti-coagulant agent

Date of first enrolment

01/10/2015

Date of final enrolment

31/03/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Oxford Haemophilia & Thrombosis Centre

Churchill Hospital

Old Road

Headington

Oxford

United Kingdom

OX3 7LE

Sponsor information**Organisation**

Oxford University Hospitals NHS Trust

Sponsor details

Research & Development, Churchill Hospital, Joint Research office, Block 60

Oxford

England
United Kingdom
OX3 7LE

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Not defined

Funder Name

Blood Coagulation and Research Fund, Oxford Haemophilia and Thrombosis Centre (OHTC)

Results and Publications

Publication and dissemination plan

This study will be published as part of a MSc thesis and will also be submitted for publication as a short report in a peer reviewed journal. We will intend to publish the laboratory data within 12 months of completing the study.

Intention to publish date

31/03/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent was not obtained from the patients.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No
HRA research summary			28/06/2023	No	No