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CRYOSTAT study: To determine whether early administration of cryoprecipitate in bleeding trauma patients is possible.

Submission date
12/09/2012

Recruitment status
No longer recruiting

Registration date
13/09/2012

Overall study status
Completed

Last Edited
21/05/2015

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Injury (trauma) is a leading cause of death and disability worldwide. Around 5,400 people die in England every year, and many thousands more are left severely disabled. Uncontrolled bleeding is the main cause of death in 2 in 5 cases. Transfusion therapy (including cryoprecipitate - a frozen blood product) is an important part of treatment for major bleeding and although there are standard transfusion methods that are routinely followed in all hospitals, we are not sure whether earlier cryoprecipitate transfusion is more effective than standard practice. The aim of this study is to test if it is possible to give cryoprecipitate at an earlier time point than is the standard practice to adult trauma patients with severe bleeding. One group of patients who take part in the trial will receive early administration of cryoprecipitate in addition to standard therapy, whilst the other group will be treated according to standard therapy. The effects of the two treatments will be compared, in particular focussing on differences in blood test results, bleeding and organ failure.

Who can participate?
Adults (16 years or above) who are trauma patients admitted directly to the emergency department of participating hospitals with active bleeding requiring a transfusion.

What does the study involve?
Participants will be treated with the standard treatment for massive bleeding or receive an extra early dose of cryoprecipitate in addition to the standard therapy. The treatment to which a participant is allocated to will be decided by a process called 'randomisation', which is like a coin toss. At the end of the study we will see whether it is possible to administer cryoprecipitate more quickly to patients with severe bleeding i.e. within 90 minutes of hospital admission.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. Participants receiving early administration of cryoprecipitate might respond better, but at present we do not know if this will occur. This trial will help in the design of future studies which will enable this question to be answered. All the blood products that will be used in the CRYOSTAT study have been approved

for use in the UK and have been treated for viruses and other pathogens according to normal procedures. There is a small risk that patients receiving cryoprecipitate early may raise their blood fibrinogen level higher than those receiving standard care and this may increase the risk of blood clots. As far as we know, there are no additional risks associated with participating in this trial.

Where is the study run from?
John Radcliffe Hospital, Oxford and the Royal London Hospital, London.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in June 2012. The recruitment phase at each hospital will last 15 months. Recruitment and follow-up for the trial will last 18 months.

Who is funding the study?
NHS Blood and Transplant (NHSBT)

Who is the main contact?
Dr Simon Stanworth
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Contact information

Type(s)
Scientific

Contact name
Miss Claire Rourke

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12485

Study information

Scientific Title
A feasibility study for a multi-centre, randomised controlled trial evaluating the effects of early administration of cryoprecipitate in major traumatic haemorrhage.

Acronym
CRYOSTAT

Study objectives
The main objective of this randomised controlled trial is to test whether the early administration of cryoprecipitate, in addition to standard massive haemorrhage therapy, is feasible in adult trauma patients with haemorrhagic shock and active bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 04/05/2012, ref: 12/SC/0145

Study design
Multicentre randomised unblinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Haemorrhagic shock in trauma patients

Interventions
(A) Early cryoprecipitate in addition to standard massive haemorrhage therapy (the intervention will be 2 adult pools over 15 minutes)
(B) Massive haemorrhage therapy alone

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility:
1. Proportion of patients in the intervention arm who receive cryoprecipitate within 90 minutes of admission
2. Recruitment rate (the proportion of eligible patients enroled)

Secondary outcome measures
Clinical endpoints:
1. All cause mortality up to day 28 from randomisation
2. Bleeding outcomes, as assessed by numbers of all blood components transfused (PRBC, FFP, platelets, cryoprecipitate) at 6 hr, 24 hr and 28 days from randomisation
3. Thrombotic events; venous thromboembolism (PE, DVT), arterial events (MI, stroke) to 3 months from randomisation
4. Organ failure as defined by single or multi-organ failure, to day 28 from randomisation
5. Length of hospital stay (including ITU or HDU stay)
6. Non-acute and acute transfusion reactions deemed to be related to cryoprecipitate up to day 28 from randomisation

Laboratory endpoints:
1. Longitudinal changes in Clauss fibrinogen, and ROTEM FIBTEM/EXTEM measurements (CA and MCF) at three pre-specified transfusion time points (after 4, 8 and 12 units of red cells), at 24 hours and 72 hours from randomisation
2. Longitudinal changes in Clauss fibrinogen at days 7, 14, 21 and 28 from randomisation

Overall study start date
01/06/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Written informed consent or agreement is obtained before any study related activity
2. The participant is judged to be 16 or above in UK and is affected by traumatic injury
3. The participant is deemed by the attending clinician to have ongoing active haemorrhage on admission
AND REQUIRES
4. Activation of the local major haemorrhage protocol for management of severe blood loss

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

UK Sample Size: 40

Key exclusion criteria
1. The patient has been transferred from another hospital
2. The trauma team leader deems the patient inappropriate for the trial i.e. injuries deemed to be incompatible with life
3. More than 3 hours has elapsed from the time of injury

Date of first enrolment
01/06/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital
London
United Kingdom
E1 1BB

Sponsor information

Organisation
NHS Blood and Transplant Service (UK)

Sponsor details
John Radcliffe Hospital
Headley Way
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Sponsor type
Government

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

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
NHS Blood and Transplant (NHSBT) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No