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The intensive care study of coagulopathy part 2

Submission date
19/09/2011

Recruitment status
No longer recruiting

Registration date
10/10/2012

Overall study status
Completed

Last Edited
18/12/2018

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
This is a study of patients admitted to Intensive Care Units (ICUs) who are not bleeding, but are traditionally considered to be at the greatest risk of bleeding because they have a prolonged Prothrombin Time (PT). Prothrombin Time is the time it takes for your blood to clot and is currently the test used to measure the blood's ability to prevent bleeds, but there are newer tests that may be more effective. Transfusions of fresh frozen plasma are often given to correct prolonged PTs, but more evidence is needed to see if this is necessary. The results of this study will provide a better understanding of the relationship between the traditional blood test Prothrombin Time (PT), and the new tests, Rotational Thromboelastography (ROTEM), Thrombin Generation (TG) and Thromboelastography (TEG), that measure the body's ability to prevent bleeds. This will provide an insight into the limitations of our traditional test for assessing someone's risk of bleeding, and whether it should continue to be used, or whether the new tests should be used. By looking at whether fresh frozen plasma improves the results of the traditional and new tests, we will be better informed about whether or when to give it.

Who can participate?
If you are aged 18 and over and admitted to a participating Intensive Care Unit with a sufficiently prolonged PT, and are not actively bleeding or on treatment dose blood thinners.

What does the study involve?
Anonymous information about why participants are in intensive care will be collected, blood samples will be taken and the results of routine blood tests will be recorded daily. If participants need a transfusion, blood samples will be taken before and after the transfusion is given. Participants will take part in the study until day 5 of ICU admission or discharge from the ICU, whichever occurs first.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in the trial, but the results of this study will help inform how we measure the risk of bleeding when patients are admitted to an intensive care unit (ICU) and how we manage it.

Where is the study run from?
Addenbrooke's Hospital, Cambridge is the lead centre. Other centres that may take part are:
1. John Radcliffe Hospital, Oxford

2. Royal London Hospital, London
3. St Thomas' Hospital, London
4. Edinburgh Royal Infirmary, Edinburgh

When is the study starting and how long is it expected to run for?
The study started in May 2012 and will run for 12 months.

Who is funding the study?
CSL Behring, UK.

Who is the main contact?
Mrs Fiona Goddard
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective cross-sectional observational study of haemostatic testing in patients admitted to adult critical care with prolongation of prothrombin time without clinical bleeding

Acronym
ISOC 2

Study objectives
Prolongation of prothrombin time (PT) does not correlate well with an individuals coagulation potential, bleeding or thrombosis, and the global clotting tests Rotational Thromboelastography (ROTEM), Thrombin Generation (TG) and Thromboelastography (TEG) might be better predictors of bleeding and thrombosis. Studies evaluating the optimal management of coagulopathy in critically ill patients need to be based around better validated tests of haemostasis. Future clinical studies may then evaluate restricted, or targeted use of replacement therapies such as Fresh Frozen Plasma (FFP) or small volume prohaemostatic drugs such as Packed Cell Concentrate (PCC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee, 28/10/2011, ref:11/SC/0429

Study design
Multicentre prospective cross sectional non randomised observational study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Coagulopathy in intensive care

Interventions
Blood will be taken on enrolment, before and after Fresh Frozen Plasma transfusion or at the end of the study if no transfusion is given. The majority of patients will have central venous access or peripherally inserted central cannulae (PICC) as this is part of the routine management of a patient requiring intensive care. Where possible, samples will be taken from a central line or Peripherally Inserted Central Cannula (PICC) line as this is a painless proceedure, where neither is available, or functioning, samples will be collected by venepuncture. Venepuncture is associated with a sting on insertion of the needle, however the majority of patients on ITU will be receiving pain relief and venepuncture is routinely undertaken without pain relief. The initial blood samples required for the study will total no more than 15ml of blood. This is minimal

compared with the total volume of blood in the body, which is 5 litres and should not have a negative clinical effect. The further samples required before and after a FFP transfusion, or at the end of the study, will again be no more than 15ml.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Haemostasis will be measured using traditional coagulation tests [prothrombin time (PT), activated partial thromboplastin time (APTT), platelets, fibrinogen) and the new whole blood techniques of assessing clot formation and breakdown TG, Thrombelastography (TEG) and thromboelastometry (ROTEM).

Clotting factor levels, vWF levels, antithrombin, proteins c and s levels will be measured, in cases where there is a disproportionate difference between PT and the newer techniques of measuring coagulopathy.

Secondary outcome measures
1. The effect of transfusing FFP will be measured using traditional coagulation tests (PT, APTT, platelets, fibrinogen) and the new whole blood techniques of assessing clot formation and breakdown TG, TEG and ROTEM.
2. The number and severity of clinically significant bleeds will be recorded using a Bleeding Assessment Form

Overall study start date
02/01/2013

Completion date
02/06/2014

Eligibility

Key inclusion criteria
1. Admission to a general intensive care unit
2. Prolongation of the PT time by more than 3 seconds beyond the upper limit of the normal range for local hospital within 48 hours of admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

200

Key exclusion criteria
1. No evidence of active clinical bleeding at the time of enrolment (for example active blood loss through post-operative drains, or clinically significant bleeding, defined as an estimated total cumulative blood loss > 300ml)
2. Warfarin therapy or other treatment dose anticoagulant therapy at the time of enrolment

Date of first enrolment
02/01/2013

Date of final enrolment
02/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Health Service Blood and Transplant (NHS BT)
Oxford
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OX39BQ

Sponsor information

Organisation
NHS Blood and Transplant (NHSBT) (UK)

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Sponsor type
Government

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

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Industry

Funder Name
CSL Behring (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	01/06/2018		Yes	No