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Monitoring heparin anticoagulation in major vascular surgery

Submission date
21/09/2015

Recruitment status
No longer recruiting

Registration date
25/09/2015

Overall study status
Completed

Last Edited
12/05/2016

Condition category
Surgery

[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
Vascular surgery is a type of surgery that treats diseases of the arteries and veins. During vascular surgery the drug heparin is commonly used to stop the blood from clotting (heparin anticoagulation). If too much heparin is given the patient is at risk of excess bleeding, and if too little heparin is given the patient is at risk of blood clots during the operation. It is increasingly being seen as best practice to use methods that keep blood loss to a minimum and reduce the requirement for blood transfusion. There is a debate about the best method of monitoring heparin anticoagulation. The most commonly used test to guide heparin dosing during surgery is activated clotting time (ACT), which measures how long it takes your blood to clot. However, there are concerns about variations in response between patients, and how ACT levels relate to laboratory tests of heparin activity. The aims of this study are to compare ACT levels and laboratory tests in patients undergoing major vascular surgery, record the variation in responses to heparin in these patients, and relate heparin activity to patient outcomes such as bleeding and clotting.

Who can participate?
Adult patients undergoing elective major complex vascular surgery with heparin anticoagulation and monitoring.

What does this study involve?
All patients undergoing this type of major vascular surgery are fitted with an arterial line - a thin catheter inserted into an artery from which blood is routinely sampled at intervals throughout the surgery without having to pierce the skin repeatedly. During the study the doctor takes an extra sample of blood (equivalent to half a teaspoonful) each time blood is monitored for heparin anticoagulation. This additional blood is sent to the laboratory to undergo different tests that also monitor heparin activity. Apart from the additional blood sampling during their surgery their care is exactly the same as if they were not in the study. The patients are also followed up to assess whether they have any bleeding or blood clotting, which is part of their routine care.

What are the possible benefits and risks of participating?
There is no direct benefit from taking part in the study, but the results of this study may help

future patients and contribute to improved treatment during surgery. The disadvantages to taking part in the study are that the participant will have extra blood tests during surgery. There is no other change in the participant's treatment.

Where is the study run from?
Royal Free London NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
October 2015 to April 2017.

Who is funding the study?
Vascular Anaesthesia Society of Great Britain and Ireland (VASGBI).

Who is the main contact?
Dr Nick Schofield

Contact information

Type(s)
Scientific

Contact name
Dr Nick Schofield

ORCID ID
http://orcid.org/0000-0003-3098-455X

Contact details
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NHS REC 15/LO/1750

Study information

Scientific Title
Monitoring heparin anticoagulation in major vascular surgery: an observational cohort study

Study objectives
Aim to correlate activated clotting time (ACT), anti-Xa levels and antithrombin levels during major vascular surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research & Development Department Royal Free Hospital, 27/10/2015, REC Ref: 15/NI/0219

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Haematology and vascular surgery

Interventions
Enrolled patients will have additional blood tests during their surgery - withdrawal of additional 2.7 ml of blood with each monitoring episode. Up to an additional 16 ml of blood may be sampled during the course of surgery. This is equivalent to roughly 1 tablespoon and should not convey any additional risks or adverse consequences. Sampling episodes will be kept to a minimum and minimum volumes of blood withdrawn to reduce any avoidable wastage of blood. Blood will be taken from established invasive lines (arterial line), at the same time point as routine samples and therefore additional needling of the skin will not be necessary. Blood samples will be used to measure the activated clotting time (ACT), thrombin generation and anti-Xa levels.

Intervention Type
Other

Primary outcome measure
Correlate ACT and anti-Xa levels during aortic surgery - measured at baseline and up to six time points during surgery

Secondary outcome measures
1. Blood loss and bleeding will be measured during theatre
2. Clotting complications will be monitored during theatre and first week postoperatively

Overall study start date
05/10/2015

Completion date
05/04/2017

Eligibility

Key inclusion criteria
All adult patients able to give informed consent and undergoing elective major complex vascular surgery in which heparin anticoagulation and monitoring is indicated

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. <18 years old
2. Unable to consent
3. History of heparin allergy
4. Already taking part in research study

Date of first enrolment
05/11/2015

Date of final enrolment
05/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free London NHS Foundation Trust
Pond Street
Hampstead

London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Free London NHS Foundation Trust (UK)

Sponsor details
Pond Street
Hampstead
London
England
United Kingdom
NW3 2QG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Other

Funder Name
Vascular Anaesthesia Society of Great Britain and Ireland (VASGBI) Departmental Project Grant DG01-2015

Results and Publications

Publication and dissemination plan
To be confirmed at 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