

Monitoring heparin anticoagulation in major vascular surgery

Submission date 21/09/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/05/2016	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Contact details

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United Kingdom

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Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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)

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

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