

A study to assess the feasibility and effects of introducing remote ischaemic preconditioning in elective abdominal aorta aneurysm repair

Submission date 16/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/08/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

An abdominal aneurysm is an enlarged and weakened section of the abdominal aorta - the main artery that carries blood from the heart. As an aneurysm increases in size it can split open, which carries a very high risk of death. Therefore, when it reaches a certain size it is best to repair it surgically before it becomes dangerous. During this operation the surgeon replaces the weak section in the aorta with a graft. To do this the surgeon will clamp the artery above and below the aneurysm to prevent blood flowing through the area during surgery. This situation, when blood flow to an organ is cut off, is called ischaemia. When the blood supply to an organ returns after a period of ischaemia (a process called reperfusion), damage can occur. The absence of oxygen and nutrients during ischaemia creates a condition in which the restoration of the blood supply results in inflammation and damage to tissues. This can lead to heart and kidney problems and even death. However, we know that if the blood supply is first halted for a short time and then restored quite quickly the tissue cells seem to learn to deal with later, longer periods of loss of blood flow in a process called ischaemic preconditioning. Studies suggest that ischaemic preconditioning may protect the heart and other organs during big operations. In this study we wish to investigate if remote ischaemic preconditioning (done in a simple and safe way by inflating a normal blood pressure cuff on the patient's arm for 5 minutes) protects the patient and reduces heart and kidney problems after abdominal aneurysm operations. The aim is to assess the feasibility and consequences of remote ischaemic preconditioning and the value of conducting a larger study to accurately assess its full usefulness as part of routine care.

Who can participate?

Patients aged 30 to 100 undergoing elective abdominal aorta aneurysm repair.

What does the study involve?

Before undergoing surgery participants were randomly allocated to receive either remote ischaemic preconditioning or a sham procedure. Remote ischaemic preconditioning was applied by inflating a blood pressure cuff on the arm of the patient for 3 cycles of 5 minutes, allowing 5 minutes of reperfusion in between.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Southmead Hospital (UK).

When is the study starting and how long is it expected to run for?
December 2010 to December 2012.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
Dr Ronelle Mouton
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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
9300

Study information

Scientific Title

A study to assess the feasibility and effects of introducing remote ischaemic preconditioning in elective abdominal aorta aneurysm repair: a randomised controlled pilot study

Study objectives

In this study we are piloting the introduction of remote ischaemic preconditioning (RIPC) in patients undergoing elective surgery for repair of abdominal aortic aneurysm (AAA), using a simple, non-invasive, non-surgical technique. We wish to determine the feasibility and acceptability of the procedure and to inform a proposal to conduct an adequately powered, multi-centre Phase III randomised controlled trial (RCT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West 5 REC, 29/07/2010, ref: 10/H0107/36

Study design

Randomised; Interventional; Design type: Not specified

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 sheet

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Valve Disease

Interventions

60 subjects: 30 undergoing elective abdominal aneurysm repair via the traditional open procedure (15 in RIPC arm and 15 controls)

30 undergoing endovascular aorta aneurysm repair (EVAR) with again 15 patients per arm for RIPC and controls

Remote ischaemic preconditioning applied by inflating a blood pressure cuff on the arm of the patient to 40mmHg above normal systolic blood pressure. The intervention is applied for 3 cycles of 5 mins, allowing 5 mins of reperfusion inbetween.

Intervention Type

Procedure/Surgery

Primary outcome measure

The main outcomes of this pilot trial relate to the planning requirements for the multi-centre RCT, including key information on recruitment method and consent procedures and rates, patient and clinical staff acceptability and opinion, data on the logistics of the delivering the RIPC, blinding, data collection and capture, management processes, and expected variations in practice across sites.

Primary clinical outcomes recorded in the pilot trial are renal injury and myocardial injury, including arrhythmias and myocardial infarction.

Secondary outcome measures

1. The length of ICU stay and duration of overall postoperative hospital stay
2. Incidence of stroke and death
3. Variation in patient-reported outcomes

We shall use variation in these outcomes to inform power calculations for the larger RCT, taking information on procedural differences between centres into consideration.

Overall study start date

01/12/2010

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Over a 24-month period all new patients presenting to Southmead Hospital for elective AAA repair will be invited to participate in the trial
2. Upper Age Limit 100 years; Lower Age Limit 30 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

1. Unable to give informed consent
2. If they are taking sulphonylurea oral hypoglycaemic drugs or nicorandil, which have been shown to influence preconditioning

Date of first enrolment

01/12/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

Sponsor details

Trust Headquarters

Beckspool Road

Frenchay

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United Kingdom

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit Programme (RfPB)

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	25/08/2015		Yes	No