

Study into the effects of ischaemic pre-conditioning (IPC) on ischaemia-reperfusion injury (IRI) in patients with peripheral vascular disease

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2016	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0436130382

Study information

Scientific Title

Study into the effects of ischaemic pre-conditioning (IPC) on ischaemia-reperfusion injury (IRI) in patients with peripheral vascular disease

Study objectives

The aim of this study is to show that both local and remote pre-conditioning is protective against reperfusion injury in high risk subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Peripheral vascular disease

Interventions

Laboratory study; Randomised controlled trial; Qualitative methodology.

Exercise on treadmill until symptoms of reperfusion injury are reproduced. This is preceded by preconditioning exercises (warm up exercises) in some cases vs no preconditioning exercises in other cases.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Reduction in complications of reperfusion injury as measured by

1. Metabolites
 - 1.1. Lactate
 - 1.2. Blood pH
 - 1.3. Interleukin 6 (IL-6)
 - 1.4. Heat shock protein (HSP)
 - 1.5. Nitric oxide (NO)
2. Blood constituents
 - 2.1. Activated platelets
 - 2.2. Platelet-leucocyte aggregates

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2003

Completion date

01/04/2005

Eligibility**Key inclusion criteria**

Study group - volunteers selected from patients with peripheral vascular disease (outpatients) who experience symptoms of claudication; control subjects will be age-matched volunteers.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2003

Date of final enrolment

01/04/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Vascular Surgical Unit

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust 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