

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	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/09/2016	Condition category Circulatory System	☐ Individual participant data ☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Vascular Surgical Unit
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration