ISRCTN18883083 https://doi.org/10.1186/ISRCTN18883083

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
Prof S Homer-Vanniasinkam

Contact details
Vascular Surgical Unit
Clarendon Wing
Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 2947
shervanthi.homer-vanniasinkam@leedsth.nhs.uk

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 preceeded 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