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Does remote ischaemic preconditioning reduce heart and cerebral damage following carotid endarterectomy? A randomised controlled trial

Submission date 15/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/01/2006	**Overall study status** Completed	
Last Edited 17/08/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Carotid endarterectomy is associated with a significant risk of stroke or myocardial infarction. This trial aims to determine whether remote ischaemic preconditioning reduces subclinical cerebral and myocardial damage among patients undergoing carotid endarterectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reviewed and approved by an NHS Research Ethics Committee November 2005. The committee will review the results of the first 12 block randomised patients to determine if the trial should proceed any further.

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
Carotid stenosis

Interventions
Patients randomised to undergo ischaemic preconditioning will have a thigh cuff inflated on one leg until flow in the pedal arteries disappears. After five minutes have elapsed, the cuff will be moved to the opposite thigh. The cycle will be repeated so that each leg has two five minute periods of ischaemia followed by five minutes of reperfusion.
Control: no ischaemic preconditioning.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary neurological outcome: proportion of patients developing a significant change in saccadic latency as determined by quantitative oculometry.
Cardiac outcome: serial troponin I levels post-operatively.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Patients undergoing elective carotid endarterectomy.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Patients with an ankle-brachial pressure index less than 0.7
2. Patients who have undergone previous lower limb amputation
3. Blind patients

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Vascular Surgeon
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.addenbrookes.nhs.uk

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Cambridge Vascular Research Fund (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2010		Yes	No