

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
Registration date 13/01/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2007

Eligibility

Key inclusion criteria

Patients undergoing elective carotid endarterectomy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Consultant Vascular Surgeon

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)**Funder type**

Charity

Funder Name

Cambridge Vascular Research Fund (UK)

Results and Publications**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