

Do vascular patches inserted after carotid endarterectomy serve any purpose?

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2008	Condition category Circulatory System	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0287023110

Study information

Scientific Title

Study objectives

Use of vascular patches following carotid endarterectomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 2008: study received ethical approval LREC No: 97/306

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Carotid endartectomy

Interventions

The insertion of a vascular patch following carotid endartectomy has been sporadically used after many years, but is of no proven worth. Advocates of patch insertion suggest that the vessel patency rate is higher, the chances of thrombosis lower and the chances of re-stenosis also lower. There is no scientific basis to support this notion. In this study we wish to randomise patients undergoing carotid endartectomy into those having a patch versus those in whom the vessel is repaired conventionally.

We will measure the blood flow velocity in the middle cerebral artery before and after removal of the clamps as is conventional and we will compare the vessel patency rate at 3 and 12 months, in the two groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added July 2008:

Clinical Outcome at 4 and 12 months

Secondary outcome measures

Added July 2008:

Vessel Patency at 4 and 12 months

Overall study start date

20/01/1998

Completion date

03/12/2003

Eligibility

Key inclusion criteria

Carotid endarterectomy patients

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added July 2008: 315 patients

Key exclusion criteria

Added 2008:

Unable to give informed consent or refused consent to participate

Date of first enrolment

20/01/1998

Date of final enrolment

03/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Box No 167
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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	01/10/2006		Yes	No