

Do vascular patches inserted after carotid endarterectomy serve any purpose?

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/07/2008	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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular: Carotid endarterectomy

Interventions

The insertion of a vascular patch following carotid endarterectomy 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 endarterectomy 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(s)

Added July 2008:

Clinical Outcome at 4 and 12 months

Key secondary outcome(s)

Added July 2008:

Vessel Patency at 4 and 12 months

Completion date

03/12/2003

Eligibility

Key inclusion criteria

Carotid endarterectomy patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Box No 167

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

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