ISRCTN19452561 https://doi.org/10.1186/ISRCTN19452561

Do vascular patches inserted after carotid endartectomy serve any purpose?

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2008	Circulatory System	

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

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

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(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
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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