

Carotid And Vertebral Artery Transluminal Angioplasty Study

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/10/2017	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
MC1

Study information

Scientific Title
Carotid And Vertebral Artery Transluminal Angioplasty Study: Carotid And Vertebral Artery Transluminal Angioplasty Study

Acronym

CAVATAS Study

Study objectives

Atherosclerosis of the carotid and vertebral arteries in the neck is an important cause of stroke and transient ischaemic attack (TIA). Previous randomised clinical trials have demonstrated that the risks of stroke are significantly reduced by carotid surgery in suitable patients with recent symptoms and severe carotid stenosis. However, surgery has the disadvantage of an incision in the neck which may lead to cranial or superficial nerve injury and wound complications. There is also a significant risk of a stroke caused by the operation and a small risk of myocardial infarction. Carotid surgery is often performed under general anaesthesia, adding further to the potential for complications. Treatment of carotid stenosis by new endovascular techniques using balloon dilation (angioplasty) or stenting avoids a surgical incision and uses only local anaesthetic, but the risks and benefits of endovascular treatment were uncertain. We therefore compared endovascular treatment with conventional treatment in a multicentre international randomised trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular diseases: Cerebrovascular disease

Interventions

561 patients were entered in three arms of the trial between 1992 and July 1997. Patients with carotid stenosis suitable for surgery (n=504) were randomised between endovascular treatment and carotid surgery. Patients with carotid stenosis unsuitable for surgery (n=40) and patients with vertebral artery stenosis (n=17) were separately randomised between endovascular treatment and medical care alone. The data from these last 2 groups has not yet been published. The main analysis was restricted to the 504 patients with carotid stenosis randomised between endovascular treatment (n=251) or surgery (n=253). Stents were used in 55 (22%) randomised to endovascular treatment; the remainder were treated by balloon angioplasty alone. Patients were followed up by an independent neurologist.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Survival free of disabling stroke

Key secondary outcome(s)

Any stroke or death within 30 days of treatment, myocardial infarction within 30 days of treatment, treatment-related cranial nerve palsy or haematoma requiring reoperation or prolonging hospital stay. Stenosis (>70%) and occlusion on ultrasound follow-up. Stroke during follow-up. Further treatment procedure. Quality of life and economic measures.

Completion date

31/07/1997

Eligibility

Key inclusion criteria

For inclusion in the study patients had to have stenosis of the common carotid artery, carotid bifurcation, internal carotid artery or extracranial vertebral artery that investigators considered suitable for endovascular treatment.

Patients eligible for surgery and patients ineligible for surgery were studied and randomised as two separate groups.

Investigators included patients only if the best treatment was unclear i.e. patients were randomly assigned only if they and their carotid or vertebral stenosis were equally suitable for both endovascular treatment and the alternative treatment (surgery or best medical care).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Exclusion criteria included patients unable or unwilling to undergo one of the alternative treatment strategies, or who were unable to give informed consent, or if they had a disabling stroke with no useful recovery of function within the region supplied by the treatable artery. Patients were not eligible for the study if angiography showed thrombus in the affected artery, severe intracranial stenosis beyond the skull base, or a stenosis unsuitable for endovascular treatment e.g. because of tortuous vascular anatomy. However, patients did not need to have catheter angiography if a reliable non-invasive investigation had confirmed stenosis. Patients were not excluded if contraindications were noted after random assignment. There was no age limit.

Date of first enrolment

01/01/1992

Date of final enrolment

31/07/1997

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Clinical Neurology

London

United Kingdom

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Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Date Date Peer Patient-

Output type Details		created added reviewed? facing?			
Results article	results #1 [Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomised trial.]	02/06/2001		Yes	No
Results article	results #2 [Endovascular treatment with angioplasty or stenting versus endarterectomy in patients with carotid artery stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS)]	01/10/2009		Yes	No
Results article	results #3 [Long-term risk of carotid restenosis in patients randomly assigned to endovascular treatment or endarterectomy in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomised trial.]	01/10/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes