

# Carotid And Vertebral Artery Transluminal Angioplasty Study

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| <b>Submission date</b><br>23/01/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>23/01/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>04/10/2017       | <b>Condition category</b><br>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

**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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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

WC1N 3BG

## 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? |
|---|--|------------|------------|-----------|---------|
| <a href="#">Results article</a>               | 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      |
| <a href="#">Results article</a>               | 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      |
| <a href="#">Results article</a>               | 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      |
| <a href="#">Participant information sheet</a> | Participant information sheet  | 11/11/2025 | 11/11/2025 | No        | Yes     |
| <a href="#">Study website</a>                 | Study website  | 11/11/2025 | 11/11/2025 | No        | Yes     |