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Carotid And Vertebral Artery Transluminal Angioplasty Study

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2017	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cavatas.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.ion.ucl.ac.uk/cavatas_icss/downloads/Infosheet.pdf

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 measure
Survival free of disabling stroke

Secondary outcome measures
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.

Overall study start date
01/01/1992

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

Age group

Adult

Sex
Both

Target number of participants
561

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
England

United Kingdom

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)

Sponsor details

The Department of Health
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
NHS Cardiovascular Disease and Stroke National Research and Development Programme

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 #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 #3 [Long-term risk of carotid restenosis in patients randomly assigned to endovascular treatment or endarterectomy in the Carotid and				

Results article	Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomised trial.]	01/10/2009	Yes	No