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# A randomised comparison of the risks, benefits and cost effectiveness of primary carotid stenting with cartotid endarterectomy: International Carotid Stenting Study

**Submission date**
15/04/2005

**Recruitment status**
No longer recruiting

**Registration date**
12/09/2005

**Overall study status**
Completed

**Last Edited**
25/08/2023

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
About 85% of strokes are ischemic strokes, in which the blood flow to the brain is blocked by a blood clot (ischaemia). As we age, deposits of a fatty substance called plaque can build-up in the main arteries in the neck (carotid arteries). Over time, this plaque can greatly reduce the diameter of the arteries (stenosis), even blocking them all together (occlusion). If the artery is particularly stenosed (with a reduction in diameter of more than 50%) surgical treatment may be recommended to restore blood flow, reducing the risk of stroke. Traditionally, this is done using a procedure called a carotid endarterectomy, in which the blockage itself is removed through a surgical incision (cut). Carotid angioplasty and stenting is an alternative, less invasive procedure which is becoming more popular. This is considered to be a good alternative to open surgery as it is less risky and so can be used for people who are too unwell for an endarterectomy. It is done by placing a thin tube (catheter) into a large artery (usually in the leg) and guiding it to the stenosed carotid artery. A small balloon is then inflated to “flatten” the blockage against the artery wall and a stent (small mesh tube) is placed inside in order to keep the artery open. The aim of this study is to compare the risks and benefits of these two procedures in patients with carotid stenosis.

Who can participate?
Adults over 40 years of age with a narrowing of their carotid arteries of at least 50%.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive a carotid endarterectomy procedure. This involves a small cut being made in the narrowed section of the affected artery (accessed through a cut in the neck), so that the plaque can be removed by the surgeon before it is stitched closed again. Participants in the second group receive carotid artery stenting. This involves the surgeon inserting a catheter (thin tube) into the main artery of the leg (femoral artery) and guiding it up to the narrowed carotid artery with help from a special dye visible on a type of x-ray (angiogram). A guide wire inside the catheter is then

used to manoeuvre the stent and balloon into the carotid artery. The balloon is placed inside the stent and inflated in order to open the stent and push it into place against the artery wall. The balloon is then deflated and removed, leaving the stent in place. Participants in both groups are then followed up in order to record the number of people who suffer from a stroke or die.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
May 2000 to December 2010

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Professor Martin Brown
m.brown@ion.ucl.ac.uk

### Study website
http://www.cavatas.com

# Contact information

### Type(s)
Scientific

### Contact name
Prof Martin M Brown

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
A randomised comparison of the risks, benefits and cost effectiveness of primary carotid stenting with cartotid endarterectomy: International Carotid Stenting Study

### Acronym
ICSS

### Study objectives
Added as of 07/02/2007:
To compare the risks, benefits and cost effectiveness of a treatment policy of referral for carotid stenting compared with referral for carotid surgery, in patients with symtomatic carotid stenosis.

### 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 sheet available at: http://www.ion.ucl.ac.uk/cavatas_icss/downloads/Infosheet.pdf

### Health condition(s) or problem(s) studied
Carotid stenosis/stroke

### Interventions
Patients will be randomised in equal proportions to be treated by carotid endarterectomy or stenting.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Added as of 07/02/2007:
1. Any stroke or death
2. MI Within 30 days of treatment

### Secondary outcome measures
Added as of 07/02/2007:
1. Cranial nerve palsy within 30 days of treatment
2. Haematoma caused by treatment requiring surgery
3. Transfusion or prolonging hospital stay
4. Stenosis greater than 70% or occlusion during follow up
5. Further treatment of the randomised artery by interventional radiology techniques or surgery after the initial attempt
6. Quality of life
7. Health status
8. Health Service costs

### Overall study start date
01/05/2000

### Completion date
31/12/2010

## Eligibility

### Key inclusion criteria
1. Symptomatic, extracranial, internal or bifurcation, atheromatous carotid artery stenosis that is suitable for both stenting and surgery and is deemed by the randomising clinician to require treatment
2. The severity of the stenosis of the randomised artery should be at least 50% (as measured by the North American Symptomatic Carotid Endarterectomy Trial [NASCET] method or non-invasive equivalent)
3. Symptoms must have occurred in the 12 months before randomisation. It is recommended that the time between symptoms and randomisation should be less than 6 months, but patients with symptoms occurring between 6 and 12 months may be included if the randomising physician considers treatment indicated
4. The patient must be clinically stable following their most recent symptoms attributable to the stenotic vessel
5. Patients must be willing to have either treatment, be able to provide informed consent, and be willing to participate in follow up
6. Patients must be able to undergo their allocated treatment as soon as possible after randomisation
7. Any age greater than 40 may be included. There is no upper age limit.
8. Patients should only be randomised if the investigator is uncertain which of the two treatments is best for that patient at that time

### Participant type(s)

Patient

### Age group
Adult

### Sex
Both

### Target number of participants
36

### Key exclusion criteria
1. Patients refusing either treatment
2. Patients unable or unwilling to give informed consent
3. Patients unwilling or unable to participate in follow up for whatever reason
4. Patients who have had a major stroke with no useful recovery of function within the territory of the treatable artery
5. Patients with a stenosis that is known to be unsuitable for stenting prior to randomisation because of one or more of:
5.1. Tortuous anatomy proximal or distal to the stenosis
5.2. Presence of visible thrombus
5.3. Proximal common carotid artery stenotic disease
5.4. Pseudoocclusion ('string sign')
6. Patients not suitable for surgery due to anatomical factors e.g. high stenosis, rigid neck
7. Patients in whom it is planned to carry out coronary artery bypass grafting or other major surgery within 1 month of carotid stenting or endarterectomy
8. Carotid stenosis caused by non-atherosclerotic disease e.g. dissection, fibromuscular disease or neck radiotherapy
9. Previous carotid endarterectomy or stenting in the randomised artery
10. Patients in who common carotid artery surgery is planned
11. Patients medically not fit for surgery
12. Patients who have a life expectancy of less than two years due to a pre-existing condition, e.g. cancer

### Date of first enrolment
01/05/2000

### Date of final enrolment
31/12/2010

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**University College London**
London
United Kingdom
WC1N 3BG

# Sponsor information

**Organisation**
University College London (UK)

**Sponsor details**
Gower Street
London
England
United Kingdom
WC1E 6BT

**Sponsor type**
University/education

**ROR**
https://ror.org/02jx3x895

# Funder(s)

**Funder type**
Government

**Funder Name**
Medical Research Council (MRC) (UK)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# 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 | initial RCT results | 01/05/2007 | | Yes | No |
| Results article | computed tomographic measurement results | 01/11/2007 | | Yes | No |
| Results article | results | 20/03/2010 | | Yes | No |
| Results article | sub-study results | 01/04/2010 | | Yes | No |
| Results article | cognition effect results | 13/09/2011 | | Yes | No |
| Results article | hypertension results | 01/12/2011 | | Yes | No |
| Results article | results | 01/01/2013 | | Yes | No |
| Results article | results | 01/03/2013 | | Yes | No |
| Results article | blood flow velocity results | 01/06/2013 | | Yes | No |
| Results article | white-matter lesions results | 01/09/2013 | | Yes | No |
| Results article | flow velocities in the external carotid artery results | 01/10/2013 | | Yes | No |
| Results article | results | 01/01/2014 | | Yes | No |
| Results article | predictors for acute and persisting periprocedural ischemic brain lesions results | 01/02/2014 | | Yes | No |
| Results article | results | 01/04/2014 | | Yes | No |
| Results article | results | 01/11/2014 | | Yes | No |
| Results article | results | 07/02/2015 | | Yes | No |
| Results article | results | 17/02/2015 | | Yes | No |
| Results article | results | 01/12/2015 | | Yes | No |
| | results | 01/01 | | | |

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|---|---|---|---|---|---|
| Results article | | /2016 | | Yes | No |
| Results article | results | 01/03 /2016 | | Yes | No |
| Results article | results | 01/05 /2017 | | Yes | No |
| Other publications | secondary analysis | 01/07 /2018 | | Yes | No |
| Results article | results | 01/11 /2018 | | Yes | No |
| Results article | results | 01/08 /2019 | 06/08 /2019 | Yes | No |
| Results article | results | 01/11 /2019 | 27/09 /2019 | Yes | No |
| Other publications | Secondary observational prospective cohort analysis | 24/08 /2023 | 25/08 /2023 | Yes | No |