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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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Added as of 07/02/2007:
1. Any stroke or death
2. MI Within 30 days of treatment

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
University College London
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
University College London (UK)

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

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	01/01			

Results article		/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 article	results	01/01 /2016		Yes	No
Results article	results	01/03 /2016		Yes	No
Results article	results	01/05 /2017		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 analysis	01/07 /2018		Yes	No
Other publications	Secondary observational prospective cohort analysis	24/08 /2023	25/08 /2023	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