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Stent-protected Percutaneous Angioplasty of the Carotid artery versus Endarterectomy

Submission date	Recruitment status	[_] Prospectively registered
15/06/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.space.stroke-trial.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stent-protected Percutaneous Angioplasty of the Carotid artery versus Endarterectomy

Acronym
SPACE

Study objectives
To compare carotid endarterectomy (CEA) and carotid stenting in patients with symptomatic >70% carotid artery stenosis.
To prove equivalence in the treatment of symptomatic >70% carotid artery stenosis in:
a. Prevalence of ipsilateral stroke (modified Rankin ≥4) or death at 30 days
b. Prevalence of ipsilateral stroke or death within 24 months after randomisation
c. Restenosis (>70%) according to North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria at 6, 12, 24 months
d. Procedural failure: technical or serious adverse events (SAE), subacute occlusion, (re)stenosis of 70% NASCET within 7 days
e. Prevalence of any stroke within 30 days and 2 years after randomisation

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

Health condition(s) or problem(s) studied
Stroke, secondary prevention

Interventions
Carotid endarterectomy or Carotid artery stenting

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Occurrence of an ipsilateral stroke (ischaemic stroke and/or intracerebrale bleeding with symptoms lasting more than 24 hours) or the death of every cause, between randomisation and day 30

Secondary outcome measures
1. Ipsilateral stroke (ischaemic stroke and/or intracerebral bleeding) or vascular death within the follow-up period of 24 months, beginning with the time of randomisation
2. Restenosis with at least 70% measured by Duplexsonography according to 70%-stenosis following the ECST-criteria or at least a 50%-stenosis after the criteria of the NASCET after 6, 12 and 24 months
3. Procedural technical failure (technically not feasible treatment, serious adverse events [SAE] during and/or by the treatment, occlusion of the vessel or restenosis with at least 70% measured by Duplexsonography according to 70%-stenosis following the ECST-criteria or at least a 50%-stenosis after the criteria of the NASCET on the 6th day ± 1 day and 30th day ± 3 day after treatment)
4. Ipsilateral stroke (ischaemic stroke and/or intracerebral bleeding with an impairment ≥3 on the modified Rankin scale) or death of every cause, between randomisation and day 30 ± 3 after treatment
5. Strokes of every localisation and severity 30 ± 3 days after the intervention
6. Strokes of every localisation and severity within 24 months ± 14 days after the intervention

Overall study start date
01/03/2001

Completion date
31/12/2005

Eligibility

Key inclusion criteria
a. Symptomatic (Amaurosis fugax, transient ischemic attack [TIA], prolonged reversible ischaemic neurologic deficit [PRIND], complete stroke), Stenosis of the carotid bifurcation or the internal carotid artery (ICA) within 180 days before randomisation
b. Clinical impairment not more than 3 of the modified Rankin scale
c. Age at least 50 years
d. Negative pregnancy test for women with childbearing potential
e. Possibility to participate on the follow-up visits
f. Written informed consent
g. Stenosis of the carotid bifurcation or the ICA on the clinically symptomatic side with at least 70% according the criteria of the European Carotid Surgery Trial (ECST) or at least 50% after the criteria of the NASCET

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1900

Key exclusion criteria
a. Intracranial bleeding within the last 90 days before treatment
b. Uncontrolled hypertension
c. Proved intracranial vessel malformation (aneurysm or arteriovenous malformation [AVM])
d. Known cardiac cause of thromboembolism
e. Concomittant disease that will prevent the patient from attending follow up or known malignancy
f. Not correctable coagulation abnormality
g. Contraindication against Heparin, acetylsalicylic acid (ASA), Ticlopidine, or Clopidogrel
h. Contraindication against contrast medium
i. Occlusion of the common carotid artery (CCA) or ICA
j. Stenosis by an external compression (e.g. by tumour)
k. Stenosis caused by dissection
l. Restenosis after surgical or endovascular treatment
m. Radiation-induced stenosis
n. Fibromuscular dysplasia
o. Thrombusformation within the stenosis
p. Tandemstenosis if the distal stenosis is more severe than the proximal one
q. Planned simultaneous surgical procedures

Date of first enrolment
01/03/2001

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Germany

Study participating centre
Department of Neurology
Heidelberg
Germany
69120

Sponsor information

Organisation
Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung) (BMBF) (Germany)

Sponsor details
Hannoversche Straße 28-30
Berlin
Germany
10115

Sponsor type
Government

Website
http://www.bmbf.de

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Industry

Funder Name
Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung) (BMBF)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
German Research Foundation ((Deutsche Forschungsgemeinschaft) (DFG)

Funder Name
Guidant

Funder Name
Boston Scientific

Funder Name
Sanofi-Aventis

Funder Name
German Neurological Society

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	01/10/2004		Yes	No
Results article	results	01/03/2013		Yes	No
Results article	results	01/11/2018		Yes	No
Results article	results	01/08/2019	06/08/2019	Yes	No