# Stent-protected Percutaneous Angioplasty of the Carotid artery versus Endarterectomy

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
15/06/2005		☐ Protocol		
Registration date 02/08/2005	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

Prof Werner Hacke

#### Contact details

Department of Neurology Im Neuenheimer Feld 400 Heidelberg Germany 69120

# 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  $\pm$  1 day and 30th day  $\pm$  3 day after treatment)
- 4. Ipsilateral stroke (ischaemic stroke and/or intracerebral bleeding with an impairment  $\geq 3$  on the modified Rankin scale) or death of every cause, between randomisation and day 30  $\pm$  3 after treatment
- 5. Strokes of every localisation and severity  $30 \pm 3$  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