

# Stent-protected angioplasty in asymptomatic carotid artery stenosis vs endarterectomy: two two-arm clinical trials

<b>Submission date</b> 07/11/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/09/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of this study is to compare up-to-date medical (conservative) treatment (BMT) including lifestyle modification with carotid artery stenting (CAS) and carotid endarterectomy (CEA) in addition to those conservative treatments in the treatment of individuals with asymptomatic atherosclerotic carotid artery stenoses.

### Who can participate?

Patients with asymptomatic stenosis of the extracranial carotid artery. Asymptomatic means without stroke or stroke-like symptoms attributable to the target stenosis within the previous 180 days.

### What does the study involve?

Patients are allocated to one of the two substudies based on the decision of the including physician and the patient's preference: either CEA (SPACE2a substudy) or CAS (SPACE2b substudy). Patients in the SPACE2a study will be randomly allocated to receive either CEA + BMT or BMT alone, while those in the SPACE2b study will be randomly allocated to receive either CAS + BMT or BMT alone. BMT is defined as the best medical treatment of hypertension, blood glucose and hyperlipidemia according to current guidelines.

### What are the possible benefits and risks of participating?

The benefit from every treatment is the proposed reduction of future cerebrovascular and cardiovascular events. Each treatment arm carries specific risks. Risks from the conservative treatment are mainly due to possible side effects of the medication. The most important risk of both CAS and CEA is the risk of periprocedural stroke.

### Where is the study run from?

University hospitals of Heidelberg, Kiel and Munich (technical university).

When is the study starting and how long is it expected to run for?

Recruitment of subjects started in October 2009. The overall duration of the trial is expected to be about 9 years.

Who is funding the study?

German Research Council (Deutsche Forschungsgemeinschaft [DFG]), Germany.

Who is the main contact?

Prof. Werner Hacke

Werner.Hacke@med.uni-heidelberg.de

### **Study website**

<http://www.space-2.de/de/home/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Werner Hacke

### **Contact details**

Department of Neurology

University of Heidelberg

Im Neuenheimer Feld 400

Heidelberg

Germany

69120

+49 (0)6221 568211

Werner.Hacke@med.uni-heidelberg.de

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## **Study information**

### **Scientific Title**

Stent-protected angioplasty in asymptomatic carotid artery stenosis vs endarterectomy: a randomised, controlled, open, multi-centre study

**Acronym**

## SPACE-2

### Study objectives

Current hypothesis as of 19/12/2013:

Two separate superiority trials of interventions versus best medical treatment (BMT) are designed. The decision for one type of intervention is made (carotid endarterectomy [CEA] = SPACE2a or carotid artery stenting [CAS] = SPACE2b) prior to randomization. In both studies (SPACE2a and SPACE2b) the interventional treatment groups (CEA and CAS) will be compared with best medical treatment (BMT) separately. In addition, data from the CEA and CAS groups will be compared in an explorative manner.

Protocol can be found at: <http://www.space-2.de/de/service/03/>

Previous hypothesis:

1. Superiority of stent-protected angioplasty or carotid endarterectomy (CEA) as compared to best medical treatment with respect to the composite primary endpoint
2. Stent-protected angioplasty is not inferior to carotid endarterectomy with respect to the composite primary endpoint

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Ethics Committee of the University of Heidelberg, 20/10/2008, ref: S-311/2008
2. Ethics Committee of the University of Heidelberg gave approval on change of study design (amendment 25.09.2012) on 04/04/2013

### Study design

Randomised controlled open multi-centre study with two two-arm clinical trials

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Can be found at: <http://www.space-2.de/downloads/SPACE-2%20Patienteninformation.pdf>  
(German only)

### Health condition(s) or problem(s) studied

Asymptomatic moderate to severe stenosis of the extracranial carotid artery

### Interventions

Current interventions as of 19/12/2013:

Patients are allocated to one of the two substudies based on the decision of the including physician and the patient's preference: either CEA (SPACE2a substudy) or CAS (SPACE2b substudy). Patients in the SPACE2a study will be randomly allocated to receive either CEA + BMT or BMT alone, while those in the SPACE2b study will be randomly allocated to receive either CAS + BMT or BMT alone. BMT is defined as optimal medical treatment of hypertension, blood glucose and hyperlipidemia according to current guidelines.

Previous interventions:

1. BMT alone
2. Stent-protected angioplasty and BMT
3. Carotid endarterectomy and BMT

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Cumulative rate of events consisting of:

1. Any stroke within 30 days of treatment
2. Death from any cause within 30 days
3. Ipsilateral ischaemic stroke within five years

## **Secondary outcome measures**

1. All single components of the primary endpoint clusters
2. Any stroke, vascular death or myocardial infarction within 30 days (five years)
3. Any ischaemic stroke within 30 days (five years)
4. Disabling stroke within 30 days (five years)
5. Technical failure of intervention
6. Rate of re-stenosis (NASCET more than or equal to 50%)
7. Rate of myocardial infarction (30 days)

## **Overall study start date**

01/03/2009

## **Completion date**

12/12/2019

# **Eligibility**

## **Key inclusion criteria**

Sonographic identification of a more than or equal to 50% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) of the extracranial carotid artery in a patient (both genders, age limit 85 years) without symptoms attributable to the target stenosis within the previous 180 days.

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

85 Years

**Sex**

Both

**Target number of participants**

2 x 1636

**Total final enrolment**

513

**Key exclusion criteria**

Non-atherosclerotic origin of carotid stenosis.

**Date of first enrolment**

09/07/2009

**Date of final enrolment**

12/12/2014

## **Locations**

**Countries of recruitment**

Austria

Germany

Switzerland

**Study participating centre**

**University of Heidelberg**

Heidelberg

Germany

69120

## **Sponsor information**

**Organisation**

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

**Sponsor details**

Kennedyallee 40  
Bonn  
Germany  
53175  
+49 (0)228 885 1  
postmaster@dfg.de

**Sponsor type**

Research council

**Website**

<http://www.dfg.de>

**ROR**

<https://ror.org/018meiw64>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Deutsche Forschungsgemeinschaft

**Alternative Name(s)**

German Research Association, German Research Foundation, DFG

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Germany

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/08/2009		Yes	No
<a href="#">Results article</a>	results	01/06/2016		Yes	No
<a href="#">Results article</a>	results	15/03/2019	04/08/2020	Yes	No
<a href="#">Results article</a>		01/10/2022	20/09/2022	Yes	No