

# Decompressive surgery for the treatment of malignant infarction of the middle cerebral artery 2

<b>Submission date</b> 14/01/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/03/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Version 1

# Study information

## Scientific Title

Decompressive surgery for the treatment of malignant infarction of the middle cerebral artery 2: a prospective randomised open controlled multicentre comparative trial

## Acronym

DESTINY 2

## Study objectives

In patients older than 60 years with space-occupying malignant supra-tentorial ischaemic infarcts, decompressive hemicraniectomy significantly decreases mortality or very severe disability, and improves disability, functional neurological deficit, and quality of life compared to conservative intensive care treatment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Submitted to Ethical Committee I, Medical Faculty, University of Heidelberg (Ethikkommission I der Medizinischen Fakultät, Universität Heidelberg), is expected to pass in February/March 2009

## Study design

Prospective randomised open controlled multicentre phase III comparative trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Malignant space-occupying middle cerebral artery infarction

## Interventions

1. Decompressive hemicraniectomy
2. Conservative intensive-care medical treatment

The total duration of treatment is individual, usually less than 2 weeks, but may be longer. The last follow-up will be after 1 year for all arms.

## **Intervention Type**

Other

## **Phase**

Phase III

## **Primary outcome measure**

Modified Rankin Scale score, dichotomised 0 - 4 versus 5 - 6 after 6 months.

## **Secondary outcome measures**

1. Median time of survival after 1 year
2. Mortality after 1 year
3. NIHSS score after 1 year
4. mRS score after 1 year
5. mRS score, dichotomised 0 - 3 versus 4 - 6 after 1 year
6. Barthel-Index after 1 year
7. Stroke Impact Scale after 1 year
8. Aachen Aphasia Test after 1 year
9. Hamilton Depression Scale after 1 year
10. Complications related to surgery after 1 year

## **Overall study start date**

01/03/2009

## **Completion date**

01/01/2013

# **Eligibility**

## **Key inclusion criteria**

1. Aged 61 years or older, either sex
2. Clinical signs and symptoms of an unilateral middle cerebral artery (MCA) infarction
3. National Institutes of Health Stroke Scale (NIHSS) greater than 15 (infarcts of the non-dominant hemisphere) or greater than 20 (infarcts of the dominant hemisphere)
4. Level of consciousness (LoC) at inclusion greater than 0 (LoC greater than or equal to 1) on item 1a of the NIHSS
5. Symptom onset greater than 12 and less than 48 hours before operation or admission to the Intensive Care Unit (ICU)
6. Neuroradiological findings: unilateral ischaemic infarction of the MCA territory, involving the complete or subtotal territory, and at least partially including the basal ganglia. An additional involvement of the anterior cerebral artery (ACA) or posterior cerebral artery (PCA) territories is optional. These criteria may be evident either in initial neuroimaging or in any follow-up:
  - 6.1. Magnetic resonance imaging (MRI) or non-contrast computed tomography (CT): diffusion lesion involving the complete or subtotal unilateral MCA territory, at least partially involving the basal ganglia
  - 6.2. Evidence of space-occupying brain oedema (midline shift, compression of lateral ventricle or third ventricle)
7. Possibility to start treatment within 6 hours after randomisation
8. Informed consent by the patient or his/her legal representative

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

Maximum of 160

**Key exclusion criteria**

1. Pre-morbid modified Rankin Scale (mRS)
2. Pre-morbid mRS score less than or equal to 2 or Barthel-Index less than 95
3. Coincidental or timely associated other brain damage (i.e. trauma and others)
4. Absence of pupil reflexes
5. Glasgow Coma Score (GCS) less than 6 at randomisation
6. Secondary space-occupying haemorrhage in the area of infarction (PH2)
7. Known systemic bleeding disorder or coagulation disorder
8. Life expectancy less than 3 years
9. Other concomitant severe disease that would confound with treatment
10. Other clear contraindication for treatment
11. Pregnancy

**Date of first enrolment**

01/03/2009

**Date of final enrolment**

01/01/2013

**Locations****Countries of recruitment**

Germany

**Study participating centre**

University of Heidelberg

Heidelberg

Germany

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**Sponsor information****Organisation**

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

### **Sponsor details**

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### **Sponsor type**

Research council

### **Website**

<http://www.dfg.de/>

### **ROR**

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

## **Funder(s)**

### **Funder type**

Research council

### **Funder Name**

German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: JU 2764/1-1)

## **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?
<a href="#">Protocol article</a>	protocol	01/02/2011		Yes	No
	results				

[Results article](#)

20/03/2014

Yes

No