

# Hemicraniectomy After Middle cerebral artery infarction with Life-threatening Edema Trial

<b>Submission date</b> 16/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2014	<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

**Contact name**  
Dr Hendrik Bernardus van der Worp

**Contact details**  
P.O. Box 85500  
HP G.03.228  
Utrecht  
Netherlands  
3508 GA  
+31 (0)30 2509111  
h.b.vanderworp@umcutrecht.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2002B138

# Study information

## Scientific Title

## Acronym

HAMLET

## Study objectives

In patients with space-occupying hemispheric infarction, decompressive surgery not only reduces mortality substantially, but also improves functional outcome in survivors, as compared with conservative treatment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the medical ethical committees of all participating centres.

## 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

Ischaemic stroke; space-occupying hemispheric infarction

## Interventions

Patients will be randomised to either surgical or conservative treatment. Randomisation will be stratified for the intended mode of conservative treatment (intensive care versus stroke unit care; see below). The choice of conservative treatment is left at the discretion of the local investigator, but will usually depend on the standard mode of treatment in the participating centre. Decompressive surgery will consist of a large hemicraniectomy and a duraplasty.

## Intervention Type

Other

## Phase

Not Applicable

**Primary outcome measure**

Score on the modified Rankin Scale (mRS) at one year

**Secondary outcome measures**

The scores on the NIH Stroke Scale (NIHSS), the Barthel Index (BI), and the Montgomery and Asberg Depression Rating Scale (MADRS) and quality of life as measured with the SF36 and a visual analogue scale (VAS) at one year. In addition, the mRS, NIHSS, and BI will also be determined at 3 and 6 months, and the mRS, BI, MADRS, and SF36 also at 3 years after randomisation.

**Overall study start date**

01/09/2002

**Completion date**

01/10/2007

## Eligibility

**Key inclusion criteria**

Patients may be enrolled in the study if all of the following criteria are met:

1. Diagnosis of acute ischaemic stroke in the territory of the middle cerebral artery, with an onset within 96 hours prior to the planned start of the trial treatment
2. Score on the National Institutes of Health Stroke Scale (NIHSS) greater than or equal to 16 for right-sided lesions or greater than or equal to 21 for left-sided lesions
3. Gradual decrease in consciousness to a score of 13 or lower on the Glasgow Coma Scale (GCS) for right-sided lesions, or an eye and motor score of 9 or lower for left-sided lesions
4. Ischaemic changes on computed tomography (CT) involving two thirds or more of the territory of the middle cerebral artery (MCA), and space-occupying oedema formation. Displacement of midline structures on CT is not a requirement for inclusion.
5. Age 18 up to and including 60 years
6. Possibility to start trial treatment within 3 hours after randomisation
7. Written informed consent by a representative of the patient

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

112

## **Key exclusion criteria**

Patients will be excluded from the study for any of the following reasons:

1. Ischaemic stroke of the entire cerebral hemisphere (anterior, middle, and posterior cerebral artery territories)
2. Decrease in consciousness (partially) explained by a cause other than oedema formation, such as metabolic disturbances or medication
3. Two fixed dilated pupils
4. Treatment with a thrombolytic agent in the 12 hours preceding randomisation
5. Known systemic bleeding disorder
6. Pre-stroke score on the modified Rankin Scale greater than 1 or less than 95 on the Barthel Index
7. Life expectancy less than 3 years
8. Other serious illness that may confound treatment assessment

## **Date of first enrolment**

01/09/2002

## **Date of final enrolment**

01/10/2007

## **Locations**

### **Countries of recruitment**

Netherlands

### **Study participating centre**

**P.O. Box 85500**

Utrecht

Netherlands

3508 GA

## **Sponsor information**

### **Organisation**

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands)

### **Sponsor details**

P.O. Box 300

The Hague

Netherlands

2501 CH

info@hartstichting.nl

### **Sponsor type**

Research organisation

**Website**

<http://www.hartstichting.nl>

**ROR**

<https://ror.org/05nxhgm70>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands) (ref: 2002B138)

## 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	11/09/2006		Yes	No
<a href="#">Results article</a>	results	01/05/2013		Yes	No
<a href="#">Results article</a>	results	01/09/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2013		Yes	No