

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

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details results	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article		01/05/2013	Yes	No
Results article	results	01/09/2013	Yes	No
Results article	results	01/10/2013	Yes	No
Protocol article	protocol	11/09/2006	Yes	No