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

Submission date	Recruitment status	[_] Prospectively registered
16/06/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2014	Circulatory System	

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
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
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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?
Protocol article	protocol	11/09/2006		Yes	No
Results article	results	01/05/2013		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	results	01/10/2013		Yes	No