

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

Submission date 14/01/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 05/02/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/03/2014	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Eric Juettler

Contact details
University of Heidelberg
Im Neuenheimer Feld 400
Heidelberg
Germany
D-69120
+49 (0)6221 56 38155
eric.juettler@med.uni-heidelberg.de

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Prospective randomised open controlled multicentre phase III comparative trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

D-69120

Sponsor information

Organisation

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

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research council

Funder Name

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

Results and Publications

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?
Results article	results	20/03/2014		Yes	No
Protocol article	protocol	01/02/2011		Yes	No