ISRCTN21702227 https://doi.org/10.1186/ISRCTN21702227

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

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

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

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 Facultat, Universitat 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
D-69120

Sponsor information

Organisation

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

Sponsor details
Kennedyallee 40
Bonn
Germany
D-53175
+49 (0)0228/885-1
postmaster@dfg.de

Sponsor type
Research council

Website
http://www.dfg.de/

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

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 results	01/02/2011		Yes	No

Results article	20/03/2014	Yes	No