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Magnesium in Aneurysmal Subarachnoid Haemorrhage

Submission date	Recruitment status	[X] Prospectively registered
04/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/08/2016	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
2006-003523-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR50

Study information

Scientific Title
Magnesium in Aneurysmal Subarachnoid Haemorrhage (MASH): a phase III clinical trial

Acronym
MASH

Study objectives
The MASH study is a prospective randomised, placebo-controlled, international multi-centre trial to determine whether magnesium reduces the frequency of poor outcome (death or dependence) in patients admitted within four days after aneurysmal subarachnoid haemorrhage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from local ethics committee

Study design
Multi-centre randomised double-blind placebo-controlled parallel-group 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Aneurysmal subarachnoid haemorrhage

Interventions
Magnesium sulphate 64 mmol/day (or placebo) is started intravenously as soon as possible after informed consent and continued until 20 days after the haemorrhage.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Magnesium sulphate

Primary outcome measure
Poor outcome (dependence or death) 3 months after the subarachnoid haemorrhage (Rankin 0 - 3 versus Rankin 4 - 5, or death) as assessed with the modified Rankin scale during a telephone interview. Dependence will be defined as a Rankin score greater than 3.

Secondary outcome measures
1. No symptoms 3 months after the subarachnoid haemorrhage (Rankin 0 versus Rankin 1 - 5 or death)
2. Global change in Rankin score

Overall study start date
01/01/2006

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Aneurysmal subarachnoid haemorrhage

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. Renal failure (creatinine greater than 150)
2. Age less than 18 years
3. Weight less than 50 kg
4. No informed consent
5. Death is imminent

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
University/education

Funder Name
University Medical Centre Utrecht (UMCU) (The Netherlands)

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?
Other publications	meta-analysis	01/09/2011		Yes	No
Results article	results	07/07/2012		Yes	No
Results article	substudy results	01/10/2015		Yes	No