

Magnesium in Aneurysmal Subarachnoid Haemorrhage

Submission date 04/08/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 04/08/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/08/2016	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 Walter M. van den Bergh

Contact details
PO Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 2508350
w.m.vandenbergh@neuro.azu.nl

Additional identifiers

Clinical Trials Information System (CTIS)
2006-003523-36

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/01/2011

Eligibility

Key inclusion criteria

Aneurysmal subarachnoid haemorrhage

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/04pp8hn57>

Funder(s)**Funder type**

University/education

Funder Name

University Medical Centre Utrecht (UMCU) (The Netherlands)

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