ISRCTN19943732 https://doi.org/10.1186/ISRCTN19943732

Intravenous MAGnesium Efficacy in Stroke

Submission date 23/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2000	**Overall study status** Completed	
Last Edited 14/07/2014	**Condition category** 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
G9702465

Study information

Scientific Title

Acronym
IMAGES

Study objectives
To determine if magnesium sulphate therapy is an effective and safe treatment for acute stroke. Magnesium does not cause the same troublesome side-effects affecting many other neuroprotective compounds

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval information added as of 19/07/2007: In the UK the study has Multicentre Research Ethics Committee approval. Local institutional review boards have approved it in centres across five continents.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
The study aims to review the efficacy of intravenous magnesium as a treatment for acute stroke when compared to placebo. Pre-clinical animal models of acute stroke show that magnesium has similar efficacy to other neuroprotective compounds. Clinical trials of magnesium show that it is safe and well tolerated.

A subgroup analysis of patients recruited within the 1-6 h, patients with haemorrhagic stroke and those with lacunar cortical events will be undertaken.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
The primary endpoint of the study is the proportion of patients dead or disabled at 90 days. Comparison between groups will be by intention to treat analysis. Disability will be measured by the Barthel Index. Patients scoring greater than or equal to 60 will be considered independent and those scoring less than 60 will be considered disabled. Patients who die will be allocated a Barthel score of 0. Overall mortality and disability by Rankin Score will also be carried out.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1997

Completion date
29/02/2004

Eligibility

Key inclusion criteria
1. Clinically diagnosed acute stroke with limb weakness
2. Symptoms present for at least 1 h and treatment initiation possible within 12 h of onset
3. Aged 18 or older
4. Previously independent in activities of daily living

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2700

Key exclusion criteria
1. Co-existing disease likely to prevent outcome assessment.
2. Known chronic renal impairment.
3. Known intracerebral pathology other than stroke e.g. intracranial abscess, subarachnoid haemorrhage, brain tumour.
4. Known indication or contraindication for magnesium therapy.

5. Coma.
6. Concomitant experimental therapy.
7. Pregnancy.

Date of first enrolment
01/10/1997

Date of final enrolment
29/02/2004

Locations

Countries of recruitment
Australia

Canada

China

Scotland

Singapore

United Kingdom

United States of America

Study participating centre
The University Department of Medicine and Therapeutics
Glasgow
United Kingdom
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/04/2000		Yes	No