

# Intravenous MAGnesium Efficacy in Stroke

<b>Submission date</b> 23/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

Scotland

Australia

Canada

China

Singapore

United States of America

**Study participating centre**

**The University Department of Medicine and Therapeutics**

Glasgow

United Kingdom

G11 9NT

## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

# 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?
<a href="#">Results article</a>	results	01/04/2000		Yes	No