

Randomised Controlled Trial of Adrenocorticotrophic hormone and Magnesium for Infantile Spasms

Submission date 30/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/05/2010	Condition category Nervous System Diseases	<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

Contact name

Prof Li-Ping Zou

Contact details

Department of Neurology
Beijing Childrens Hospital
The Capital University of Medical Sciences
Beijing
China
100045
+86 (0)10 6802 8401 ext 2314
zouliping21@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

RCTAMIS

Study objectives

In this study it is hypothesised that magnesium sulphate in infantile spasms could lead to seizure rate reduction (seizure free rate) and a gradual improvement in background pattern of Electroencephalogram (EEG) (amplitude integrated Electroencephalogram [aEEG]).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Beijing Children Hospital Research Ethics Association is an independent, self-governing body of Research Ethics Committees, local and multi-centre, including their members and administrators. The Research Ethics Committee reviewed Dr Zou Li-Pings proposal for research on human subjects so as to protect them from undue risk or unethical research, while also encouraging research of high quality. Approval was received on the 1st December 2006.

Study design

Randomised controlled three group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Child neurology, epilepsy

Interventions

Patients will be randomised into one of three groups:

1. ACTH 25 IU/d and 10 Glucose fluid for Venous transfusion (GV) 100 ml (continued for greater than four hours) for three weeks
2. Magnesium Sulphate (MgSO₄) 250 mg/kg (1ml/kg) and 10 GV (1) (continued for greater than

four hours) for three weeks. If no effect, change to group three for three weeks
3. ACTH and MgSO₄: group one design and group two group design for three weeks

If we find that the patient has any of the infections mentioned in the exclusion criteria, the treatment will be stopped.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Adrenocorticotrophic Hormone (ACTH) and magnesium

Primary outcome measure

Seizure rate reduction: response to therapy was divided into the following categories: 29 - 0%, 69 - 30% and 99 - 70% reduction of spasms frequency as compared with baseline, and seizure-free status, respectively.

Secondary outcome measures

1. EEG changes: close to normal, measured at day zero, one week, two weeks, three weeks, one month, three months and six months
2. Calcium (Ca), Magnesium (Mg) and Glucose (Glu) were measured at day zero, one week, two weeks, three weeks, one month, three months and six months
3. Neuron-Specific Enolase (NSE) levels were measured at day zero, one month, three months and six months
4. Gesell Development Scale at day zero and six months

Overall study start date

30/03/2007

Completion date

30/03/2007

Eligibility

Key inclusion criteria

Primary or adjunctive therapy for infantile spasms; diagnostic criteria of International League Against Epilepsy (ILAE) greater than six spasms per day

Participant type(s)

Patient

Age group

Child

Sex

Not Specified

Target number of participants

40 cases

Key exclusion criteria

1. Patients with no infantile spasms; diagnostic criteria of ILAE greater than six spasms per day
2. Patient has one of the following infections:
 - 2.1. Septic infections
 - 2.2. Pneumonias
 - 2.3. Urinary/gastrointestinal infections
 - 2.4. Chickenpox or measles
 - 2.5. Arterial hypertension
 - 2.6. Electrolyte disturbances

Date of first enrolment

30/03/2007

Date of final enrolment

30/03/2007

Locations**Countries of recruitment**

China

Study participating centre

Department of Neurology

Beijing

China

100045

Sponsor information**Organisation**

Beijing Childrens Hospital (China)

Sponsor details

c/o Professor Li-Ping Zou

Department of Neurology

The Capital University of Medical Sciences

Beijing

China

100045

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04skmn292>

Funder(s)

Funder type

Government

Funder Name

The following are responsible for the payment of 50% of the costs to this trial:

Funder Name

The National Science Foundation of Beijing (China)

Funder Name

The Capital Development Foundation of Beijing (China)

Funder Name

The remaining 50% of the trial costs will be covered by the parents of the children in the study.

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	01/04/2010		Yes	No