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Randomised Controlled Trial of Adrenocorticotropic hormone and Magnesium for Infantile Spasms

Submission date
30/03/2007

Recruitment status
No longer recruiting

Registration date
16/07/2007

Overall study status
Completed

Last Edited
04/05/2010

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
1

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

Study type(s)
Treatment

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)
Adrenocorticotropic Hormone (ACTH) and magnesium

Primary outcome(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Sex
Not Specified

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)

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

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