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Is magnesium an effective treatment for organophosphate poisoning?

Submission date	Recruitment status	[X] Prospectively registered
31/07/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/07/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/02/2015	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

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
071669

Study information

Scientific Title
Is magnesium an effective treatment for organophosphate poisoning?

Study objectives
Is magnesium effective in reducing mortality from acute Organophosphate Poisoning (OP)?

Due to a delay to the beginning of the trial, the overall trial start date is now 03/03/2007. The overall trial end date was also therefore changed to 03/03/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Sri Lankan Medical Association Ethical Review Committee (Approval ERC/05-005), 05/08/2005.
2. Australian National University Human Ethics Research Committee (Approval 2005/195), 29/10/2005

Study design
Multicentre double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Organophosphate poisoning

Interventions
We plan to conduct a double-blind randomised controlled trial of the effectiveness of early magnesium treatment in preventing death. Patients will be randomised to magnesium sulphate or a placebo in a 2:1 ratio. (i.e 200 patients will receive magnesium and 100 patients will receive placebo).

All patients will continue to receive standard treatment. This standard treatment is determined by the attending physician who maintains clinical responsibility for all patients. While there may be some minor variation between hospitals current care consists of patient resuscitation, gastrointestinal decontamination when indicated, atropinisation and the use of pralidoxime (typically one gram every six hours). All treatment is recorded by the research team. This intervention represents an added treatment to the existing standard of care.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
The primary outcome will be the number of patients dying in those receiving magnesium versus those receiving placebo.

Key secondary outcome(s))
Secondary outcomes will include need for ventilation, blood pressure, level of consciousness and duration of atropine therapy. Adverse events reported by doctors will be rated by them as to the likelihood of them being due to magnesium infusion (certain, probable, possible, unlikely).

Completion date
03/03/2009

Eligibility

Key inclusion criteria
Patients with symptomatic acute OP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who do not consent
2. Pregnant women
3. Patients less than 16 years of age
4. Patients who are hypotensive (blood pressure less than 90/50 mmHg) on presentation and not responding to intravenous (iv) fluids and atropine
5. Patients who have ingested other substances in addition to OP
6. Patients with other major medical conditions (e.g. cardiovascular disease renal or hepatic failure)

Date of first enrolment
30/08/2006

Date of final enrolment
03/03/2009

Locations

Countries of recruitment
Sri Lanka

Study participating centre

SACTRC
Peradeniya
Sri Lanka
20000

Sponsor information

Organisation
South Asian Clinical Toxicology Research Collaboration (SACTRC) (Sri Lanka)

ROR
https://ror.org/04z435g27

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration