

# Is magnesium an effective treatment for organophosphate poisoning?

<b>Submission date</b> 31/07/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/02/2015	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

### **Secondary outcome measures**

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).

### **Overall study start date**

30/08/2006

### **Completion date**

03/03/2009

## **Eligibility**

### **Key inclusion criteria**

Patients with symptomatic acute OP

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

300

### **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)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.sactrc.org>

**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

## 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