

Clonidine in organophosphate pesticide poisoning

Submission date 20/07/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/07/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/01/2009	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☐ 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 clonidine an effective treatment in organophosphate pesticide poisoning? A phase II randomised controlled trial

Acronym

SACTRC

Study objectives

What is the safe and effective clonidine regimen in Organophosphate (OP) poisoning that will:

1. Reduce mortality and/or the need for ventilation
2. Provide moderate sedation
3. Not cause symptomatic adverse effects on blood pressure

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sri Lankan Medical Association Ethics Review Board approved on 5th August 2005 (ref: ERC/05-008)

Primary study design

Interventional

Study design

Phase II multicentre dose-finding study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Organophosphate poisoning

Interventions

Four dose levels of clonidine will be studied with the dose increased if the results in the preceding sixteen patients do not indicate any concerning dose-related adverse effects. Four patients will receive placebo and twelve patients will receive active treatment at each dose level. 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

Phase II

Drug/device/biological/vaccine name(s)

Clonidine

Primary outcome(s)

The primary outcome will be the number of patients requiring ventilation or dying in those receiving clonidine versus the placebo group.

Key secondary outcome(s)

Secondary outcomes will include:

1. Need for ventilation
2. Blood pressure
3. Level of consciousness
4. Duration of atropine therapy
5. Death
6. Adverse events reported by doctors will be rated by them as to the likelihood of them being due to Clonidine bolus or infusion (certain, probable, possible, unlikely)

Completion date

03/03/2008

Eligibility**Key inclusion criteria**

Patients (male or female, aged 16 years or older) with symptomatic acute OP poisoning.

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
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

18/05/2006

Date of final enrolment

03/03/2008

Locations

Countries of recruitment

Sri Lanka

Study participating centre

South Asian Clinical Toxicology Research Collaboration (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

The Wellcome Trust (UK) (grant ref: 071669)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration