ISRCTN89917816 https://doi.org/10.1186/ISRCTN89917816

Clonidine in organophosphate pesticide poisoning

Submission date	Recruitment status	[ ] Prospectively registered
20/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/07/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/01/2009	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

Contact name
Dr Andrew Hamilton Dawson

Contact details
South Asian Clinical Toxicology Research Collaboration (SACTRC)
Department of Medicine
University of Peradeniya
Peradeniya
Sri Lanka
20000
+94 (0)81 238 4556
adawson@sactrc.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Phase II multicentre dose-finding study

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
18/05/2006

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

Age group
Adult

Sex
Both

Target number of participants
64 (recruitment ends on 03/03/2008)

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)

Sponsor details
Department of Medicine
University of Peradeniya
Peradeniya
Sri Lanka
20000
+94 (0)81 238 4556
adawson@sactrc.org

Sponsor type
Research organisation

Website
http://www.sactrc.org

ROR
https://ror.org/04z435g27

Funder(s)

Funder type
Charity

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

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