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A trial of fructose-di-phosphate treatment in oleander poisoning

Submission date	Recruitment status	[X] Prospectively registered
15/01/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/03/2013	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
Fructose-1, 6-diphosphate (FDP) as a novel antidote for yellow oleander-induced cardiac toxicity: a randomised controlled double-blind study

Study objectives
That adding fructose-1, 6-diphosphate (FDP) to routine treatment will reverse serious arrhythmias in oleander poisoning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Peradeniya, Sri Lanka gave approval on the 24th September 2008 (ref: 2008/ec/48)

Study design
Double-blind randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiac toxicity from oleander self-poisoning

Interventions
Patients will be randomised to FDP (250 mg/kg loading dose over 20 minutes followed by 6 mg /kg/hr for 24 hours) or a placebo in a 1:1 ratio (i.e 120 patients will receive FDP and 120 patients will receive placebo). The random allocation is concealed and random sequences are generated by specially designed computer program.

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, and atropinisation. 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)
Fructose-1, 6-diphosphate (FDP)

Primary outcome(s)
Reversion to sustained sinus rhythm with a heart rate greater than 50/minute within 2 hours of completion of bolus.

Key secondary outcome(s)

1. Death
2. Reversal of hyperkalaemia on the 6, 12,18 and 24 hour samples
3. Maintenance of sinus rhythm on the Holter monitor (reflecting the efficacy of the infusion)

Completion date
20/02/2011

Eligibility

Key inclusion criteria
Patients (greater than 12 years of age, both sexes) with any of the following manifestations of oleander-induced cardiac toxicity:
1. Second degree heart block
2. Third degree heart block
3. Bradycardia with a heart rate of less than 40 beats/minute
4. Any rhythm with a systolic blood pressure below 80 mmHg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Patients with documented ischaemic heart disease or valvular heart disease. These patients may still be eligible for open label compassionate use of FDP.
2. Patients presenting with cardiac arrest on admission. These patients will be eligible for open label compassionate use of FDP.
3. Age less than 12 years

Date of first enrolment
01/02/2009

Date of final enrolment
20/02/2011

Locations

Countries of recruitment
Sri Lanka

Study participating centre
SACTRC
Peradeniya
Sri Lanka
20400

Sponsor information

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

ROR
https://ror.org/04z435g27

Funder(s)

Funder type
Charity

Funder Name
International Collaborative Research Grant:

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

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/06/2010		Yes	No