

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

Submission date 15/01/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 16/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/03/2013	Condition category Injury, Occupational Diseases, Poisoning	<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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/02/2009

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

Age group

Other

Sex

Both

Target number of participants

240

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)

Sponsor details

Faculty of Medicine

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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

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)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

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

Study outputs

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

