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

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered	
15/01/2009		[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

#### Contact name

Dr Indika Gawarammana

#### Contact details

SACTRC
Faculty of Medicine
University of Peradeniya
Peradeniya
Sri Lanka
20400
+94 (0)81 447 9822
indika@sactrc.org

#### 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

Αll

#### 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes