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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

**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

**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
University of Peradeniya
Peradeniya
Sri Lanka
20400
+94 (0)81 447 9822
enquiry@sactrc.org

### 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 |