

# Fructose-1,6-diphosphate (FDP) in yellow oleander poisoning

<b>Submission date</b> 15/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/01/2009	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Protocol serial number**  
071669; sactrc0305

## Study information

**Scientific Title**  
Phase II randomised controlled trial of fructose-1,6-diphosphate (FDP) in yellow oleander poisoning

## **Acronym**

FDP Oleander Toxicity

## **Study objectives**

Fructose-1,6-diphosphate (FDP) can reverse yellow oleander-induced cardiac toxicity in humans, specifically cardiac arrhythmia and hyperkalaemia.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Australian National University Human Ethics Research Committee (Approval 2005/208) on 16th September 2005.
2. Sri Lankan Medical Association Ethical Review Committee (Approval ERC/O5-004) on 20th July 2005.

## **Study design**

Placebo controlled, randomised phase II study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Yellow oleander-induced cardiac toxicity

## **Interventions**

A blood sample will be taken on all randomised patients at the start and end of the infusion and 30 minutes, four and 12 hours later and then at daily intervals. Serum potassium, magnesium, calcium, as well as renal function and liver function will be measured (routine clinical biochemistry methodology). The cardiac glycoside and FDP concentration will also be measured at these times.

Four dose levels of FDP will be studied with the dose doubled if the results in the preceding eight patients do not indicate any concerning dose-related adverse effects. Two patients will receive a placebo and six patients will receive active treatment at each dose level.

## **Doses:**

The first dose will be 30 mg/kg, 60% of the dose shown to be effective for this indication in dogs (50 mg/kg Intravenous [IV]). The dose will be doubled (60 mg/kg, 125 mg/kg) until 250 mg/kg assuming there is no significant toxicity attributed to the preparation at the previous dose. All these doses are well within the range of doses used in previous human studies. The highest dose is chosen as it was the most effective IV dose in one human study of ischemia/reperfusion injury post cardiac surgery (although FDP was also used in the cardioplegia solution), and larger doses (three doses of 250 mg/kg) seemed no more effective in this study and a non-significantly higher rate of acidosis and atrial fibrillation was also observed. Doses will be diluted in 5% dextrose and infused over 30 minutes with infusion pumps. Placebo infusions will be an equal volume of 5% dextrose. Drugs will be prepared shortly before use by a registered pharmacist. Treating doctors will be blind to treatment allocation.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Fructose-1,6-Diphosphate

**Primary outcome(s)**

The primary outcome will be the time to revert to continuous sinus rhythm with rate more than 44/min, in those receiving FDP versus the placebo group.

**Key secondary outcome(s)**

1. The number of patients with sinus rhythm with rate more than 44 bpm at two hours
2. Number of patients administered DigiFab
3. Other adverse events
4. Death

Secondary analysis will also compare the results at each dosing level as well as comparing trends with dose. Adverse events reported by doctors will be rated by them as to the likelihood of them being due to FDP infusion (certain, probable, possible, unlikely).

**Completion date**

01/06/2007

**Eligibility****Key inclusion criteria**

Patients (16 years of age and older, male or female) with significant cardiotoxicity will be recruited to this study, i.e. those with: 3° heart block, Mobitz type II 2° block, atrial tachyarrhythmias, sinus bradycardia with heart rate less than 35 bpm, or sinus arrest or block with sinus pauses more than 3 seconds.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. No consent
2. Pregnant

3. Less than 16 years of age
4. Ingested other cardioactive substances in addition to oleander
5. Other major medical conditions (e.g. cardiovascular disease renal or hepatic failure)

**Date of first enrolment**

01/06/2006

**Date of final enrolment**

01/06/2007

## 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)

**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**

The National Health and Medical Research Council (NHMRC) of Australia (Australia)

**Results and Publications**

**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?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes