

A randomised double blind placebo controlled trial of the efficacy of prophylactic adrenaline in the prevention of adverse reactions to anti snake venom (ASV)

Submission date 20/09/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/09/2009	Condition category 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

That subcutaneous prophylactic adrenaline reduces the number of adverse anti snake venom reactions

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Anaphylactoid or Pyrogenic reactions to anti snake venom

Interventions

Subcutaneous Adrenaline will be administered before ASV. Control: Placebo. All outcomes will be monitored.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Adrenaline

Primary outcome measure

Level of adverse reactions

Secondary outcome measures

Severity of reactions

Overall study start date

01/10/2005

Completion date

01/10/2008

Eligibility

Key inclusion criteria

1. Snakebite with systemic symptoms
2. Requirement for ASV
3. Consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Severe atopic diseases such as asthma
2. Acute cardiac conditions
3. Pregnant women and children <15 years

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

India

Study participating centre

Little Flower Hospital and Research Centre
Angamaly Kerala
India
683572

Sponsor information

Organisation

Little Flower Hospital and Research Centre (India)

Sponsor details

PB No. 23
Kalady Road
Angamaly Kerala
India
683572

Sponsor type

Hospital/treatment centre

Website

<http://www.lfsru.org>

ROR

<https://ror.org/0375jhj23>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Little Flower Hospital (India)

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