ISRCTN18411149 https://doi.org/10.1186/ISRCTN18411149

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

Registration date
29/09/2005

Last Edited
15/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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683572

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