ISRCTN29425449 https://doi.org/10.1186/ISRCTN29425449

A randomised controlled placebo based trial to determine the efficacy of a prophylactic dose of hydrocortisone and anti histamine in preventing reactions to anti snake venom (ASV)

Submission date
19/09/2005

Recruitment status
No longer recruiting

Registration date
29/09/2005

Overall study status
Completed

Last Edited
15/09/2009

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
Prof Mabel Vasnaik

Contact details
St John's Medical College
Johnagar
Bangalore
India
560034

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
A randomised controlled placebo based trial to determine the efficacy of a prophylactic dose of hydrocortisone and anti histamine in preventing reactions to anti snake venom

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 and pryogenic reactions to anti snake venom

Interventions
Either a placebo or 100 mg of hydrocortisone and 10 mg of H1 anti histamine will be administered once reqirement for ASV has been established. All outcomes will be monitored. In the event of an adverse reaction normal treatment protocols will apply.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hydrocortisone and anti histamine

Primary outcome measure
Number of anaphyalactoid and pyrogenic reactions

Secondary outcome measures
Severity of reaction

Overall study start date
01/10/2005

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Snakebite with systemic symptoms
2. Requirment for ASV
3. Have given consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
History of severe atopic diseases

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
India

Study participating centre
St John's Medical College
Bangalore

India
560034

Sponsor information

Organisation
St John's Medical College (India)

Sponsor details
Johnagar
Bangalore
India
560034

Sponsor type
University/education

ROR
https://ror.org/04z7fc725

Funder(s)

Funder type
University/education

Funder Name
St John's Medical College (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