

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	☒ Prospectively registered
Registration date 29/09/2005	Overall study status Completed	☐ Protocol
Last Edited 15/09/2009	Condition category Injury, Occupational Diseases, Poisoning	☐ 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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Contact details

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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Anaphylactoid and pyrogenic 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 requirement 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(s)

Number of anaphylactoid and pyrogenic reactions

Key secondary outcome(s)

Severity of reaction

Completion date

01/10/2008

Eligibility

Key inclusion criteria

1. Snakebite with systemic symptoms
2. Requirement for ASV
3. Have given consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/04z7fc725>

Funder(s)

Funder type

University/education

Funder Name

St John's Medical College (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration