Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical Trials of new bivalent snake antivenom immunoglobulins (IgG) for the treatment of envenoming by medically important vipers in Sindh (Phase II study)

Protocol summary

Summary

Study objective: To evaluate the estimated dose and to determine the effective dose of bivalent snake antivenom immunoglobulins (IgG) in snake bite patients. The main inclusion criteria includes: envenoming by Saw Scaled Viper and Russell's viper (Daboia Russelii); age above 18 years; 20WBCT shows incoagulable blood; with no (anaphylactic) reaction within 10-30 minutes after initial test dose of investigational product (test ASV); Patient or his/her legally acceptable representative able to understand the informed consent and enter into the study with their free will. The main exclusion criteria includes: patient refusal to take newly produced ASV as the core remedy; chronic or complicating medical conditions, any neuropathy, renal impairment, liver diseases, diabetes mellitus, Hypertension and any CV disease; hypersensitivity to horse (equine) or sheep (ovine) serum in the past and a strong history of atopic diseases (especially severe asthma). Study Population & Sample Size: Total twelve (12) Local Pakistani victims of viper snake's bite will participate; six (6) of each specie; Echis carinatus sochureki & Daboia russelii. Intervention: Intravenous administration of Bivalent snake antivenom immunoglobulins (IgG) effective against Echis carniatus and Daboia russelli envenoming found in Sindh. Initial dose: 3 vials (30ml) for Daboia russelii and 1 vial (10ml) for Echis carinatus. Outcome Measures: The dose at which maximum patients are treated (permanent restoration of blood coagulability tested by 20WBCT at 6, 12, 18 and 24 hours after dosing) with minimum toxicity. The secondary outcome includes the Incidences of anaphylactic like reactions, pyrogenic reaction and late serum sickness-type reactions

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070218314N1**
Registration date: **2014-10-07, 1393/07/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-10-07, 1393/07/15

Registrant information

Name
Naeem Quraishi
Name of organization / entity
Antisnake Venom and Antirabies Serology laboratory
Country
Pakistan
Phone
00922449370260
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Recruitment status

Recruitment complete

Funding source
Department of health, Government of Sindh, Pakistan

Expected recruitment start date

2014-10-20, 1393/07/28

Expected recruitment end date

2015-03-25, 1394/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trials of new bivalent snake antivenom immunoglobulins (IgG) for the treatment of envenoming by medically important vipers in Sindh (Phase II study)

Public title
Clinical Trial of a new snake antivenom for the treatment of viper snake bites in Sindh.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteris: Patient envenomed by Saw Scaled Viper (Echis carinatus Sochureki/ lundi) and Russell's viper (Daboia Russelii/Daman/Koriala); Adult male or female (non-pregnant) above 18 years. Reached hospital within few hours (within 0-7 hours) of snake bite. However the late reaching patients will be treated according to provincial protocol of snakebite management without inclusion in the study; Snake specie is confirmed by identification of dead snake or the clinical observation of incoagulable blood, or when a description of snake is associated with symptoms and signs consistent with systemic envenoming by viper species such as incoagulable blood, spontaneous systemic bleeding, intravascular hemolysis, (pink plasma, anemia, hemoglobinuria), acute renal failure or oliguria; 20WBCT shows incoagulable blood; Patients show no early (anaphylactic) reaction within 10-30 minutes (itching, urticaria, fever, nausea, vomiting, tachycardia, hypotension, bronchospasm) on administration of 0.3ml of test ASV as initial dose; Patient or his/her legally acceptable representative able to understand the informed consent and enter into the study with their free will by signing the same. Exclusion Criteria: Not willing to accept newly produced ASV as the core remedy; Debilitated patients and those with other chronic or complicating medical conditions, any neuropathy, renal impairment, liver diseases, diabetes mellitus, Hypertension and any CV disease; Subject with known hypersensitivity to horse (equine) or sheep (ovine) serum in the past (for example after treatment with equine anti-tetanus serum, equine anti-rabies serum or equine or ovine anti-venom) and those with a strong history of atopic diseases (especially severe asthma); Patients showing reaction to initial dose of test ASV; Patients with severe condition, acute renal failure, anuria, generalized rhabdomyolysis evident with myoglobinuria and haemoglobinuria; Pregnant women and patients under 18 years of age; not bitten by any medically important vipers of Sindh.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **12**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Single arm dose finding study

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Peoples University of medical & health sciences for women Shaheed Benazir Abad.
Street address
Peoples University of medical & health sciences for women , Shaheed Benazir Abad,
City
Nawabshah
Postal code
67450
Approval date
2014-05-14, 1393/02/24
Ethics committee reference number
IRB/IEC/lett-A01

Health conditions studied

1

Description of health condition studied
treatment of envenomation
ICD-10 code
T63.0
ICD-10 code description
Toxic effect of snake venom

Primary outcomes

1

Description
permenant restoration of blood coagulability
Timepoint
6, 12, 18 and 24 hours after dosing.
Method of measurement
measured through 20 minutes whole blood clotting test

Secondary outcomes

1

Description

early and late snake antivenom reactions

Timepoint

after test dose and ful initial dose patients will be monitored for early reaction while patients will be checked on weekly basis for next 24 days after dosing for late serum reaction.

Method of measurement

through clinical sign and symptoms and adverse evnt monitoring

Intervention groups

1

Description

Test drug: Snake antivenom immunoglobulin (IgG)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

District Headqarter Hospital Mithi and peoples medical university hospital Nawabshah

Full name of responsible person

Dr. Naeemul Haque Quraishi, Principal Investigator

Street address

Snake antivenom/antirabies serology lab, old DHo office, Sakrand road

City

Nawabshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of health, Governement of Sindh

Full name of responsible person

Dr. Hafeezul Haque Director General Health Sindh

Street address

Directorate General Health Services Sindh Wahdat Colony

City

Huderabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Department of health, Governement of Sindh

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Institute of Biochemistry University of Sindh Jamshoro

Full name of responsible person

Professor Dr. Allah Bux Ghanghro Principal Scientific Consultant

Position

Deputy Project Director

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

snake antivenom/antirabies serology lab, department of Health, Government of Sindh

Full name of responsible person

Dr. Naeemul Haque Quraishi, Principal Investigator

Position

Project Director

Other areas of specialty/work

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Person responsible for updating data

Contact
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snake antivenom/antirabies serology lab, department of Health, Government of Sindh
Full name of responsible person
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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty