

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 carinatus* and *Daboia russelii* 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

Email address

pd_naeem@asvsindh.gos.pk

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 Criteria: 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 committee 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 full 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 event monitoring

Intervention groups

1

Description

Test drug: Snake antivenom immunoglobulin (IgG)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

District Headquarter 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, Government of Sindh

Full name of responsible person

Dr. Hafeezul Haque Director General Health Sindh

Street address

Directorate General Health Services Sindh Wahdat Colony

City

Hyderabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Department of Health, Government 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

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Person responsible for updating data**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, PI

Position

Project Director

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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