# 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 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
**Email address**
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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

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snake antivenom/antirabies serology lab, department of Health, Government of Sindh
**Full name of responsible person**
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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*