

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Phase 3, multi-center, randomized, two-arm, parallel, double blinded, active controlled for non-inferiority evaluation of efficacy and safety of snake anti-venom produced by Padra Serum Alborz in comparison with snake anti-venom produced by Razi Vaccine and Serum Research Institute in snakebite victims.

Protocol summary

Study aim

Evaluation of efficacy and safety of anti-venom produced by Padra Serum Alborz

Design

An active controlled, parallel group, double blinded, randomized clinical trial

Settings and conduct

The study is double blinded, multi-center in Mashhad, Ahvaz, Shiraz and Uromia. victims will be receiving the intervention treatments randomly after inclusion /exclusion evaluation and signing of inform consent form. Quantity of required antivenoms based on physical examination, para-clinic tests and physicians diagnosis will be prepared for injection by nurse and will be infused. thirty minutes, 1, 6, 12, 48 and 72 hours after injection victims will be visited by physician and everything will be recorded in eCRF. After discharge of victim from hospital, serum sickness questioner through phone call one and two weeks after antivenom administration will be asked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian Victims of 2- 60 years of age with snake bite, signed Informed consent, hospital entrance within 12 hours of snake bite and indication of antivenom administration. Exclusion criteria: Victims with history of allergy to horse serum, history of snake bite or scorpion sting, presence of two or more numbers of bites, sea snakebite, received antivenom prior to reach to study center, Having chronic disease.

Intervention groups

Intervention group 1: Anti-venom of Padra Serum Alborz (Vial). Intervention group 2: Anti-venom of Razi (Ampule)

Main outcome variables

Stopping progression of swelling and neurotoxicity

symptoms, Normalized coagulation abnormalities till 48 hours.

General information

Reason for update

Information Updating

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039672N2**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **prospective**

Last update: **2020-11-03, 1399/08/13**

Update count: **1**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name

Maryam Amini Pouya

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase 3, multi-center, randomized, two-arm, parallel, double blinded, active controlled for non-inferiority evaluation of efficacy and safety of snake anti-venom produced by Padra Serum Alborz in comparison with snake anti-venom produced by Razi Vaccine and Serum Research Institute in snakebite victims.

Public title

Phase 3, multi-center clinical trial for evaluation of two types of snake anti-venom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of snakebite Informed consent for participating in the study Men or Women victims with age of 2 to 60 years Victims who arrive at mentioned hospitals within 12 hours after snakebite Victims who need anti-venom according to the bite severity scale Victims who have Iranian nationality (having national ID)

Exclusion criteria:

Victims with history of allergy to horse serum Victims who have experience of prior treatment with snake or scorpion antivenom due to snakebite or scorpion sting in the past. Victims with two or more number of bites on arrival at hospital. Victims who already have received antivenom prior to reach to hospital. Victims who do wound manipulation (incision, suction, burning and so on) before hospital entrance. Victims with life threatening bleeding (such as bleeding in mouth and upper respiratory tract) Victims who receive heparin and warfarin Victims with history of coagulopathy, cardiac disease, neuromuscular disease, kidney and liver failure. Pregnant or breastfeeding women. Victims who have sea snakebite. Victims who need for mechanical ventilation at the time of registration.

Age

From **2 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization sequences have been made online using

the quadruple blocks for the total sample size of 98 victims (ratio of 1:1). The produced randomization sequences would be located in the study site. Each randomization code have been already labeled on each related anti-venom (2 groups of intervention) and be presented in the study site drug stock. After assurance of victim eligibility and receiving the informed consent, according to the randomization sequence, the specific anti-venom would be injected to victims.

Blinding (investigator's opinion)

Double blinded

Blinding description

All victims after meeting the eligibility criteria are examined by physician. After allocating of randomization code to each victim, the nurse with using the drug stock in the study site (with the research tag on them) prepare the infusion bag for Intravenous infusion. Due to identical appearance of infusion bags and administration process, none of the victims would be aware of the group of intervention. It is tried to minimize the awareness of physician from the type of intervention but it's unavoidable. Importance of blindness is emphasized while education the nurses and physicians. In addition since the data are documented in eCRF as untitled codes, the data management team would receive the information without the identification of victims. Therefore, the blindness in victims and outcome assessor team would be obtained completely and for physician would be partial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Shahid Fakouri Blvd.

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Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.MUMS.REC.1398.295

2

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

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Khouzestan

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6135715794

Approval date

2020-01-02, 1398/10/12

Ethics committee reference number

IR.AJUMS.REC.1398.955

3

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

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Approval date

2020-05-13, 1399/02/24

Ethics committee reference number

IR.UMSU.REC.1399.058

4

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

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Kerman

Province

Kerman

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7616913555

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.KMU.REC.1399.336

Health conditions studied

1

Description of health condition studied

Snake-Bite

ICD-10 code

T63.0

ICD-10 code description

Toxic effect of snake venom

Primary outcomes

1

Description

Percentage of victims with improving in snakebite symptoms

Timepoint

At baseline and 48 hours after antivenom administration

Method of measurement

A) Stopping progression of swelling B) Normalized coagulation abnormalities C) Stopping the progression of neurotoxicity

Secondary outcomes

1

Description

Percentage of adverse events

Timepoint

0.5, 1, 6, 12, 24, 48, 72 hours, 7 and 14 days after Intervention

Method of measurement

Reporting the incidence proportion

2

Description

dose of antivenom administrated

Timepoint

0.5, 1, 6, 12, 24, 48, 72 hours after Intervention

Method of measurement

Number of injected vials

Intervention groups

1

Description

Intervention group: Vial containing 10 mL of sterile solution of snake antivenom produced by Padra Serum Alborz which each mL is able to neutralize more than 50 LD50. Initial dose: Moderate or severe signs and symptoms, 5 and 10 vials, respectively; Repeat dose: 1 to 6 hours after initial dose, 5 vials until symptom treatment or administration of totally 20 vials; Maintenance dose: 2 vials Infusion every 6 hours up to 3 doses.

Category

Treatment - Drugs

2

Description

Control group: Ampules containing 10 mL of sterile solution of snake antivenom produced by Razi Vaccine and Serum Research Institute which each mL is able to neutralize more than 50 LD50. Initial dose: Moderate or severe signs and symptoms, 5 and 10 ampules, respectively; Repeat dose: 1 to 6 hours after initial dose, 5 ampules until symptom treatment or administration of

totally 20 vials; Maintenance dose: 2 ampules Infusion every 6 hours up to 3 doses.

Category

Treatment - Drugs

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Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Seyed Reza Mousavi

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2

Recruitment center

Name of recruitment center

Abouzar Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Padra Serum Alborz Company

Full name of responsible person

Mohamad Amin Ghobadi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Padra Serum Alborz

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Arta Zist Pharmed

Full name of responsible person

Maryam Amini Pouya

Position

Medical department manager

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor of Forensic Medicine and Clinical

Toxicology

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available