Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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

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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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Golestan High Way

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Approval date
2020-01-02, 1398/10/12

Ethics committee reference number
IR.AJUMS.REC.1398.955

3

Ethics committee

Name of ethics committee
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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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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

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

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Recruitment center

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Name of recruitment center
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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Padra Serum Alborz Company

Full name of responsible person
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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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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