

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Phase 3 clinical trial for non-inferiority evaluation of efficacy and safety of scorpion antivenom "Padra Serum Alborz " production vs "Razi Vaccine and Serum Research Institute" in the treatment of scorpion sting victims age of 2 to 60

Protocol summary

Study aim

Non-inferiority evaluation of efficacy and safety of "Padra Serum Alborz" vs "Razi Vaccine Serum Research Institute" scorpion antivenom productions

Design

Active control, double blind, two-armed, randomized(1:1), phase 3 clinical trial designed for 98 scorpion sting victims age of 2 to 60

Settings and conduct

Scorpion sting victims who will refer to Razi hospital in Ahvaz, will be assessed for inclusion and exclusion criteria. Then they will be treated with antivenom and concomitant therapy based on the initial signs & symptoms of systemic envenomation. The victims will be reassessed 2, 6, 12 & 24 hours after first antivenom infusion in hospital. The serum sickness incidence will be evaluated after 7 & 14 days. The victim, physician and the outcome assessor are blinded about type of antivenom.

Participants/Inclusion and exclusion criteria

Inclusion: Scorpion sting victims age of 2 to 60; Arriving to hospital maximum 6 hours after scorpion sting; Signs of systemic scorpion envenomation or having the Indication for Antivenom Infusion Exclusion: History of allergic reactions to plasma derived productions; History of severe allergic diseases such as atopic asthma; Present of systemic diseases such as cardiovascular and kidney diseases; Pregnant and breast feeding women

Intervention groups

Intervention group: Scorpion Antivenom Vial (Padra Serum Alborz Production) Control group: Scorpion Antivenom Ampule (Razi Vaccine Serum Research Institute)

Main outcome variables

Alleviation of systemic scorpion envenomation (12 hours after antivenom injection)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039672N1**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**

Update count: **1**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Maryam Amini Pouya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

maryam.aminipooya@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2019-02-06, 1397/11/17

Actual recruitment end date

2019-04-16, 1398/01/27

Trial completion date

2019-04-30, 1398/02/10

Scientific title

Phase 3 clinical trial for non-inferiority evaluation of efficacy and safety of scorpion antivenom "Padra Serum Alborz " production vs "Razi Vaccine and Serum Research Institute" in the treatment of scorpion sting victims age of 2 to 60

Public title

Efficacy and safety evaluation of "Padra Serum Alborz" vs "Razi Vaccine and Serum Research Institute" scorpion antivenom productions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Scorpion sting victims age of 2 to 60 Hospital entrance at maximum 6 hours after scorpion sting Signs of systemic scorpion envenomation or having the Indication for Antivenom Infusion

Exclusion criteria:

History of allergic reactions to plasma derived productions History of severe allergic diseases such as atopic asthma Present of systemic diseases such as cardiovascular and kidney diseases Pregnant and nursing women

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **98**

Actual sample size reached: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization sequences will be made by online software using the quadruple blocks before the start of study to achieve the sample size of 98 victims. Each of these sequences will be converted to untitled code (e.g. c45, a37, ...). Antivenoms that will be presented in the study cite drug stock, have been labeled with the research label & the unique untitled code before initiation of the study. After arrival of each victim, according to the randomization sequence, the specific antivenom will be prepared by the nurse. So through the randomization process, concealment & blindness of victims, physicians & outcome assessor also would be kept.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the victim consent and according to the antivenom infusion by the nurse, the victim and physician will not

be aware of the injected antivenom brand. Also the final results will be given to outcome assessor with untitled codes. So we would expect that the blindness in victims, physicians and outcome assessor will be obtained properly.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan High Way

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-01-26, 1397/11/06

Ethics committee reference number

IR.AJUMS.REC.1397.790

Health conditions studied

1

Description of health condition studied

Scorpion sting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Proportion of victims with alleviation of scorpion envenomation symptoms

Timepoint

12 hours after antivenom infusion

Method of measurement

Symptom alleviation: Alleviate the initial symptoms from "severe" to "moderate to mild" by the physician diagnosis

Secondary outcomes

1

Description

The mean time of scorpion envenomation symptoms duration alleviation

Timepoint

24 hours after antivenom infusion

Method of measurement

The time recording

2

Description

The incidence of anaphylactic reactions

Timepoint

During the study time

Method of measurement

Reporting the incidence proportion

3

Description

The Serum Sickness incidence

Timepoint

During the study time

Method of measurement

Reporting the incidence proportion

4

Description

The incidence of any other adverse events

Timepoint

During the study time

Method of measurement

Reporting the incidence proportion

5

Description

Duration of the victims' hospitalization

Timepoint

During the study time

Method of measurement

The time recording

Intervention groups

1

Description

Intervention group: 1 to 3, 5ml vials (by physician diagnosis based on initial signs) of Scorpion Antivenom (Padra Serum Alborz Production) with dose of 10 LD50/ml for 20 to 30 minutes IV infusion

Category

Treatment - Drugs

2

Description

Control group: 1 to 3, 5ml ampules (by physician diagnosis based on initial signs) of Scorpion Antivenom

(Razi Vaccine and Serum Research Institute) with dose of 10 LD50/ml for 20 to 30 minutes IV infusion Scorpion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Ahvaz

Full name of responsible person

Ahmad Ghorbani

Street address

Felestin St., Amanieh

City

Ahvaz

Province

Khouzestan

Postal code

3318461357

Phone

+98 61 3333 5935

Email

ahmadghorbanidr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Padra Serum Alborz Company

Full name of responsible person

Mohamad Amin Ghobadi

Street address

No. 110, Khaje Nasir Tousi St., Bahman St., Sepehr Industrial Town.

City

Nazar Abad

Province

Alborz

Postal code

3331495894

Phone

+98 26 4533 4189

Email

a.ghobadi@padraserum.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Padra Serum Alborz Company

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**

Industry

3318461357

Phone

+98 61 3161

Email

ahmadghorbanidr@gmail.com

Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Padra Serum Alborz

Full name of responsible person

Maryam Amini Pouya

Position

Medical Department Maganer

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No. 110, Khaje Nasir Tousi St., Bahman St., Sepehr Industrial Town.

City

Nazar Abad

Province

Tehran

Postal code

3331495894

Phone

+98 26 4533 4189

Fax**Email**

m.amini@artapharmed.com

Contact**Name of organization / entity**

Padra Serum Alborz

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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City

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Province

Tehran

Postal code

3331495894

Phone

+98 26 4533 4189

Fax**Email**

m.amini@artapharmed.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ahmad Ghorbani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

Street address

Razi Hospital, Felestin St., Amanie

City

Ahvaz

Province

Khouzestan

Postal code**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