

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Khuzestan

##### 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**

Khuzestan

##### **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

**Street address**

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3331495894

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**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**

Khuzestan

**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