Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 sings & 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)

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+98 21 8889 6696

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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
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3318461357
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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
Street address
No. 110, Khaje Nasir Tousi St., Bahman St., Sepehr Industrial Town.
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Alborz
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3331495894
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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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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