Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluate the prophylactic role of fresh frozen plasma in reducing renal complications in children presenting with severe hemoglobinuria followed by scorpion stinging

Protocol summary

Summary

Acute kidney injury is frequently seen in stung patients with Hemiscorpius lepturus scorpion. Acute kidney injury refers to 2-fold increase in serum creatinine levels or reduced kidney filtration rate by half. In addition to decline in renal filtration, other findings suggest kidney damage are proteinuria, pyuria and hematuria. The use of fresh frozen plasma (FFP), in scorpion stung patients with hemolytic uremic syndrome (HUS) was followed by a good therapeutic results. Objectives: We decided to study the effect of FFP on the prevention of acute kidney injury and HUS in scorpion stung patients referred to Abuzar hospital, Ahvaz, Iran (as a single center study). This study is double blind and blinding is done for research analyzers. In this interventional (phase 3) study, we will include scorpion stung patients with gross hemoglobinuria and will classify them to two 48 groups as intervention and control groups. Patients with a history of renal failure or hematuria will excluded. Patents in intervention group received 10 cc/kg FFP every 12 hours for 3 days. We won't use placebo in control group. We will evaluate serum creatinine and urine protein as primary outcome and duration of hospitalization as secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903103122N2**
Registration date: **2015-09-05, 1394/06/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-05, 1394/06/14

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the prophylactic role of fresh frozen plasma in reducing renal complications in children presenting with severe hemoglobinuria followed by scorpion stinging

Public title

Fresh frozen plasma prophylaxis role in reducing renal complications of scorpions sting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Gross hemoglobinuria after scorpion

stinging; informed consent. Exclusion criteria: patients with a history of renal failure; Patients with the past history of hematuria or on the first urine test.

Age
To **15 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur university of medical sciences

Street address
Golestan Ave.

City
Ahvaz

Postal code

Approval date
2014-10-18, 1393/07/26

Ethics committee reference number
ajums.REC.1393.280

Health conditions studied

1

Description of health condition studied
Renal failure

ICD-10 code
N-17, N18,

ICD-10 code description
Renal failure

Primary outcomes

1

Description
Creatinine

Timepoint
Daily

Method of measurement
Mg/dl

2

Description
Urine Protein

Timepoint
Daily

Method of measurement
Dipstic

Secondary outcomes

1

Description
Duration of hospitalization

Timepoint
Daily

Method of measurement
Day

Intervention groups

1

Description
Intervention group: Fresh frozen plasma 10cc/kg every 12 hour for 3 days

Category
Treatment - Drugs

2

Description
Control group: We won’t use placebo in control group

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Abuzar Children Hospital

Full name of responsible person
Ehsan valavi

Street address
Abuzar Children Hospital

City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology
Full name of responsible person
Dr. Saki
Street address
Golestan Ave.
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty