

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

Ehsan Valavi

##### Name of organization / entity

Ahvaz Jundishapur University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1444 3052

##### Email address

valavi.e@ajums.ac.ir

#### 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

**Name of organization / entity**

Abouzar Hospital

**Full name of responsible person**

Ehsan Valavi

**Position**

Pediatric Nephrologist

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## Person responsible for scientific inquiries

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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*