

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Survey Efficacy of the fibrinogen and Fresh frozen plasma in the hemodynamic and clinical outcomes of patients with severe trauma

Protocol summary

Summary

Objective: Survey efficacy of the fibrinogen and Fresh frozen plasma in the hemodynamic and clinical outcomes of patients with severe trauma. Design: In this interventional study, a total of 40 consenting patients will be selected and divided in two groups using block randomization method (n=20 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: Age over 18 years old; patients with multiple trauma; need for repeated transfusion; injury severity score 16 and above; satisfaction to participate in the study. Exclusion criteria: Unwillingness of the patient to continue cooperation in the plan; trauma limited to head; Penetrating trauma; injury severity score less than 16. Setting and conduct: The first and second groups will be treated with fibrinogen extract (70 mg/kg, every 8 hours until the INR reaches under 1.8) and FFP 10 - 15 mg/kg, every 8 hours until the INR reaches under 1.8) made by Iranian Blood Transfusion Organization respectively. Blood pressure, pH level, oxygenation index 4 and 12 hours after the beginning of the intervention and Patients' demographic information, types of brain and organ damage, level of consciousness, days requiring mechanical ventilation, number of blood units taken, the occurrence of multi organ failure, the duration of hospitalization and death of the patients will be recorded in the questionnaire. Data collected will be compared between the two groups by statistical tests. Outcomes measure: Blood pressure, pH level, oxygenation index; types of brain and organ damage; level of consciousness; days requiring mechanical ventilation, number of blood units taken, the occurrence of multi organ failure, duration of hospitalization and death of the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051923559N13**

Registration date: **2017-11-05, 1396/08/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey Efficacy of the fibrinogen and Fresh frozen

plasma in the hemodynamic and clinical outcomes of patients with severe trauma

Public title

Efficacy of the fibrinogen and Fresh frozen plasma in patients with severe trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years old; patients with multiple trauma; need for repeated transfusion; injury severity score 16 and above; satisfaction to participate in the study. Exclusion criteria: Unwillingness of the patient to continue cooperation in the plan; trauma limited to head; Penetrating trauma; injury severity score less than 16.

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences Ethics committee

Street address

Shahid Beheshti University of Medicine Sciences,
Tabnak street , tehran

City

Tehran

Postal code**Approval date**

2017-06-19, 1396/03/29

Ethics committee reference number

IR.SBMU.REC.1394.33

Health conditions studied**1****Description of health condition studied**

Trauma

ICD-10 code

T79.8

ICD-10 code description

Other early complications of trauma

Primary outcomes**1****Description**

Blood pressure

Timepoint

4 and 12 hours after the beginning of the intervention

Method of measurement

Manual blood pressure monitor

2**Description**

Blood PH

Timepoint

4 and 12 hours after the beginning of the intervention

Method of measurement

Lab

3**Description**

Oxygenation index

Timepoint

4 and 12 hours after the beginning of the intervention

Method of measurement

Lab

Secondary outcomes**1****Description**

Types of brain and organ damage

Timepoint

At the beginning of the intervention

Method of measurement

Imaging through CT scan

2**Description**

Level of consciousness

Timepoint

At the beginning of the intervention

Method of measurement

Using the Glasgow Coma Score

3

Description

Days requiring mechanical ventilation

Timepoint

During hospital admission

Method of measurement

Counting the days required for mechanical ventilation

4

Description

Number of blood units taken

Timepoint

During the days of admission

Method of measurement

Count of injected blood units

5

Description

Duration of hospitalization

Timepoint

Time of discharge

Method of measurement

Count the number of admitted days

6

Description

Patients death

Timepoint

End of intervention

Method of measurement

Clinical

Intervention groups

1

Description

first group will be treated with fibrinogen extract (made in Iranian Blood Transfusion Organization, 70 mg/kg, every 8 hours until the INR reaches under 1.8)

Category

Treatment - Drugs

2

Description

second group will be treated with FFP (made in Iranian Blood Transfusion Organization, 10- 15 mg/kg, every 8 hours until the INR reaches under 1.8)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Hossein Hospital

Full name of responsible person

Dr Ehsan Akbari

Street address

Imam Hossein Hospital , Shahid Madani St., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin zargi

Street address

Shahid Beheshti University of Medical Science, Daneshjoo Blvd, Tabnak St, Chamran Highway, Tehran, Iran

City

Tehran

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, Shahid Beheshti University of Medical Sciences

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ehsan Akbari

Position

Emergency Medicine assistant

Other areas of specialty/work**Street address**

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00
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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