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
s.matin@arums.ac.ir

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
School of Medicine, Shahid Beheshti University of Medical Science, Daneshjoo Blvd, Tabnak St, Chamran Highway, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2240 3821

Fax
Email
akbari.ehsandr@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Hatamabadi
Position
Emergency Medicine Specialist
Other areas of specialty/work
Street address
School of Medicine, Shahid Beheshti University of Medical Science, Daneshjoo Blvd, Tabnak St, Chamran Highway, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2240 3821
Fax
Email
hhatamabadi@yahoo.com
Web page address

Person responsible for updating data

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
City
Postal code
Phone
00
Fax
Email
Web page address

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