Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

fibrinogen and blood requirement in trauma patients

Protocol summary

Summary

Uncontrollable and excessive blood loss is one of the inevitable elements of the mismanagement in trauma patients. In acute blood loss, fibrinogen amount decreases which in turns increases bleeding. Fibrinogen concentrate allows rapid access to fibrinogen supplementation in smaller volumes. In this randomized, double blinded and single center study, the primary outcome was comparing the effect of prophylactic fibrinogen supplementation on transfusion requirement in trauma patients.Inclusion criteria: All trauma patients. Exclusion criteria: Patients having received fibrinogen or cryoprecipitate before operation, Patients with hereditary or acquired coagulopathies and history of allergy to fibrinogen concentrate. After anesthesia induction and intubation and before the start of the surgery, patients in the control group will receive 30 mg/kg of fibrinogen concentrate (diluted in 100 mL of distilled water) within 10 minutes. Transfusion requirement in patients, determining and comparing the complications from fibrinogen concentrate and hemoglobin levels before and after surgery will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050220795N3**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

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Samad Golzari
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

fibrinogen and blood requirement in trauma patients

Public title

Effect of prophylactic fibrinogen on the need for perioperative blood transfusion in traumatic patients undergoing abdominal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All trauma patients. Exclusion criteria: Patients having received fibrinogen or cryoprecipitate before operation, Patients with hereditary or acquired coagulopathies and history of allergy to fibrinogen concentrate.

Age

No age limit

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht St., Tabriz
City
Tabriz
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
TBZMED.REC.1395.24

Health conditions studied

1

Description of health condition studied
Injury of intra-abdominal organs
ICD-10 code
S36
ICD-10 code description
Injury of intra-abdominal organs

Primary outcomes

1

Description
Transfusion requirements
Timepoint
Before and after surgery
Method of measurement
Hemoglobin levels

Secondary outcomes

1

Description
fibrinogen plasma level
Timepoint
Before and after surgery
Method of measurement
fibrinogen plasma level

Intervention groups

1

Description
Ppatients in the control group will receive 30 mg/kg of fibrinogen concentrate (diluted in 100 mL of distilled water) within 10 minutes.
Category
Treatment - Drugs

2

Description
Control group: No intervention will be made in this group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Samad Eslam Jamal Golzari
Street address
Imam Reza Hospital, Golgasht St., Tabriz
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Sponsors / Funding sources

1

Sponsor
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Tabriz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
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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