Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the fibrinogen and fresh frozen plasma efficacy in patients outcome with hemorrhagic shock due to multiple trauma

Protocol summary

Study aim

Confirmation of the role of fibrinogen and fresh frozen plasma in improving the outcome of patients with multiple traumatic hemorrhagic shock

Design

A clinical trial study (Phase III) was administered to control, randomized, double blinded patients. Sample size: 30 people (in each group ten). Randomized block randomization and block size are considered equal to 4. There are two intervention groups (A, B) and an active control group (C). Group C will receive Packed Cell, Group B, Frozen Fresh Flask and Group A Fibrinogen.

Settings and conduct

Location: Emergency hospital of Golestan and Imam Khomeini hospitals in Ahvaz city. Blindness: After evaluating an emergency medicine specialist or resident of the third year of emergency medicine residing in the CPR room and determining the placement of the patient in one of the three study groups, the prescribing instruction will be given to the nurse of the CPR department, and then the order of evaluation of the patient's vital signs will be given to the researcher. (Resident of Emergency Medicine) who has no information about how to describe the patient's placement and the type of injectable medicine to the patient.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with hemorrhagic shock caused by multiple trauma Age> 14 years Systolic blood pressure <90 mm Hg Exclusion Criteria: Pregnancy Patients with known coagulopathy Taking anti-coagulant drugs and antiplatelet drugs Other causes of shock, such as neurogenic shock Dissatisfaction of patient or patient companions to participate in the study.

Intervention groups

Control group: Patients receiving Packed Cell intervention group 1: patients receiving fresh frozen plasma intervention group 2: Patients receiving fibrinogen

Main outcome variables

Blood pressure; pH level; Oxygenation index; Multiple organ failure; Hospital duration; Death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150704023046N4**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **retrospective**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name
Mehdi Gholamzadeh Baeis
Name of organization / entity
Qom Branch Of Islamic Azad University
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the fibrinogen and fresh frozen plasma efficacy in patients outcome with hemorrhagic shock due to multiple trauma

Public title
Effect of fibrinogen compared to fresh frozen plasma on patients with hemorrhagic shock
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hemorrhagic shock caused by multiple trauma Age> 14 years Systolic blood pressure <90 mm Hg Significant chance of bleeding Evidence of intra abdominal bleeding Clinical judgment of the doctor about the receipt of blood products
Exclusion criteria:
Pregnancy Patients with known coagulopathy Using anti-coagulant and anti-platelet drugs Other causes of shock, such as neurogenic shock Previous history of blood product in the last 6 months Patients are severely ill, whose priority is to preserve the patient's health Dissatisfaction with the patient or patient companions to participate in the study
Age
From **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Accidental randomization was done using randomized blocking method in which subjects were assigned to three main groups (two intervention groups and one control group) (each group was 10) and the volume of blocks was 4 Which was determined through the PROC PLAN in SAS 9.2 software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blindness in this study is that after evaluating an emergency medicine practitioner and determining the patient's placement in one of our three study groups, the injectable drug will be given to the nurse of the CPR department, and then the order of assessment of the patient's vital signs will be researcher Emergency medicine), which has no information on how to describe the patient's placement and type of injectable medicine, is given according to the protocol.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahwaz Jundishapur Research and Technology Dept, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2018-08-29, 1397/06/07
Ethics committee reference number
IR.AJUMS.REC.1397.334

Health conditions studied

1

Description of health condition studied
Hemorrhagic shock
ICD-10 code
R58
ICD-10 code description
Hemorrhage, not elsewhere classified

2

Description of health condition studied
Hypovolemic shock
ICD-10 code
R57.1
ICD-10 code description
Hypovolemic shock

Primary outcomes

1

Description

Blood Pressure

Timepoint

4 and 12 hours after admission, 24-hour short-term prognosis, 7-day mid-term and long-term 28-day

Method of measurement

Clinical examination and assessment of vital signs by cardiac monitoring and pulse oximetry located in the cardiopulmonary resuscitation room

2

Description

Oxygenation index

Timepoint

4 and 12 hours after admission, 24-hour short-term prognosis, 7-day mid-term and long-term 28-day

Method of measurement

pulse oximetry located in the cardiopulmonary resuscitation room

3

Description

PH level

Timepoint

4 and 12 hours after admission, 24-hour short-term prognosis, 7-day mid-term and long-term 28-day

Method of measurement

By taking arterial blood samples and evaluating arterial blood gas by laboratory tests

4

Description

Duration of admission

Timepoint

When ordering a patient's discharge or issuing a death certificate

Method of measurement

Clinical examination and evaluation of patient records

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving Packed Cell and Frozen Fresh Plasma in proportion (FFP: 1: 1 PRbc Ratio). Intervention is performed for each patient at one time in the emergency CPR room. Each packed cell is approximately 200-250 cc and each frozen plasma unit is 200-300 cc.

Category

Treatment - Drugs

2

Description

Intervention group: Patients receiving Packed Cell and Fibrinogen. The amount of fibrinogen injection will be 70 mg / kg. The fibrinogen vial is made in Germany and will be provided by Avin Daru Company in Iran. Interventions are performed for each patient at one time and in the emergency CPR room.

Category

Treatment - Drugs

3

Description

Control group: Patients receiving Packed Cell. The Packed Cell available at the Blood Bank Center of the studied hospitals was used. The size of each Packed Cell is approximately 200-250 cc. The number of Packed Cell varies depending on the patient's needs and clinical conditions. Intervention is performed for each patient at one time and in the emergency CPR room.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital, Ahvaz City

Full name of responsible person

Ehsan Karimpour

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Golestan Medical Center - Farvardin Avenue - Golestan

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Deputy Research and Technology
Street address
Ahvaz Jundishapur University of Medical Sciences - Golestan
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ehsan Karimpour
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only part of the information, such as information on the main outcome or the like, can be shared.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and academic institutions and industry-related people
Under which criteria data/document could be used
Solely for the sake of scientific use and only with the permission of the owners of the design
From where data/document is obtainable
Responsible person is responsible for studying and by email registered on the site
What processes are involved for a request to access data/document
So coordinate with the responsible person responsible for the study through email registered on the site
Comments