

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 61 3391 8586

Email address

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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

Ahvaz Jundishapur Research and Technology Dept, Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Province

Khuzestan

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

Street address

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
Ahvaz University of Medical Sciences

Full name of responsible person
Deputy Research and Technology

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Ahvaz Jundishapur 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
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
Emergency Medicine

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Assistant professor

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Person responsible for updating data

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Email

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