Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of hypertonic serum in patients with hemorrhagic shock

Protocol summary

Study aim
Determining the difference between the effect of hypertonic serum and isotonic serum in patients with hemorrhagic shock

Design
An open-label randomized clinical trial with an intervention and control group, block randomization method

Settings and conduct
The study was designed as an open-label, randomized clinical trial in 440 patients with hemorrhagic shock admitted to the emergency department of Shahid Mohammadi Hospital, Bandar Abbas, Iran. Patients will be prospectively enrolled in the study and followed up. Patients will be randomly assigned to each intervention group according to 1:1 ratio between the study group (the group receiving hypertonic serum) and the control group (the group receiving standard care).

Participants/Inclusion and exclusion criteria
Inclusion criteria included age ≥18 years, physician-confirmed hemorrhagic trauma, exposure to penetrating or blunt trauma 1 hour prior to randomization, blood volume loss >1000 mL, systolic blood pressure Below 100 mmHg, informed consent to participate was included. Exclusion criteria included history of unusual medical conditions, patients transferred from other hospitals, and patients with excessive delay in the treatment process.

Intervention groups
Two intervention groups, A and B, were considered in this study. Group A will receive 250 ml of 5% hypertonic saline followed by 0.9% isotonic saline as needed to stabilize the patient. Group B will receive 250 ml of isotonic serum with a concentration of 0.9 and, if necessary, increase the amount of fluid consumed to stabilize the patient according to standard of care.

Main outcome variables
Key outcomes of this study include reduced patient mortality from hemorrhagic shock during the intervention period.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230521058246N1**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information
Name
Melika Alavitabar
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2025-07-23, 1404/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of hypertonic serum in patients with hemorrhagic

shock

Public title
Effect of hypertonic serum in patients with hemorrhagic shock
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with hemorrhagic trauma confirmed by a physician 18 years or older people In people exposed to penetrating or blunt trauma one hour before randomization In people with systolic blood pressure ≤100 mm Hg In people with informed consent regarding participation in the research In people with a decrease in blood volume (more than 1000 ml)
Exclusion criteria:
Patients with a history of high blood chloride Patients with a history of high sodium levels in the blood Patients with a history of high potassium levels in the blood Patients with a history of kidney dysfunction Patients with a history of pregnancy Patients with a history of epilepsy Patients with a history of blood coagulation-related diseases Patients with a history of liver disease Patients with a history of a severe decrease in body temperature to less than 28 degrees Celsius Patients with a history of inability to receive IV Patients with a history of absence of cardiac sinus rhythm Patients with a history of cardiac arrest Patients with a history of cardiopulmonary resuscitation Patients with a history of burns of more than 20% of the body surface Patients with a history of increased intracranial pressure Patients with a history of anaphylactic reactions Patients with tissue or cellular dehydration Patients with a history of receiving more than 2 liters of crystalloid before the study began Patients with a history of suffocation caused by hanging Patients transferred from other hospitals Patients with excessive delay in the treatment process
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **440**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method In this method, the number of people in each study group is equal to each other during the treatment. Considering the number of 440 participants (220 in each group) and the approximate duration of 10 months to complete the study, 11 blocks of 40 will be used. The work method in this type of randomization is similar to the simple randomization method. , only the number of people during the treatment period is the same in the two treatment groups. The only drawback of this method is the identification of the last group in each block.
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
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Research and Technology vice-chancellor Building,Hormozgan University of Medical Science Campus,Imam Hossein Blvd,Bandar Abbas,Iran
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Approval date
2023-04-24, 1402/02/04
Ethics committee reference number
IR.HUMS.REC.1402.019

Health conditions studied

1

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

Primary outcomes

1

Description
The primary outcome of this study include a decrease in the mortality rate of patients due to hemorrhagic shock during the intervention period.
Timepoint
Upon discharge
Method of measurement
Patient's File

Secondary outcomes

1

Description
Reducing the length of hospital stay
Timepoint
Upon discharge
Method of measurement
Patient's File

2

Description
Reducing the length of ICU stay
Timepoint
Upon discharge
Method of measurement
Patient's File

3

Description
Reducing the volume of blood and fluids received
Timepoint
After intervention
Method of measurement
Check list and patient's file

Intervention groups

1

Description
Intervention group: Group A receives 250 ml of hypertonic saline with a concentration of 5%, and then, according to standard treatments, isotonic saline with a concentration of 0.9% is used to stabilize the patient. If the patient's condition is not stabilized, blood will be injected into the patient, and these people will be excluded from the study.
Category
Treatment - Other

2

Description
Intervention group: Group B receives 250 ml of isotonic saline with a concentration of 0.9%, and then, if required, according to standard treatments, the amount of fluid received is increased until the patient is stabilized, and if the patient's condition is not stable, blood is injected, in this case, the patient will be excluded from the study.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The Great Prophet Research and Educational Complex Research Center
Full name of responsible person
Dr. Sadegh Ahmadi Rashti
Street address
Educational and Research Complex of the Great Prophet,Shahid Mohammad Hospital, Jomhory Blvd,Old Airport,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Vali Alipor
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Web page address
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dr. Sadegh Ahmadi Rashti

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available