Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of hemodynamic effects of bicarbonate infusion in hemorrhagic shock

Protocol summary

Study aim

Determination of hemodynamic effects of bicarbonate infusion in patients with hemorrhagic shock

Design

A Study of clinical trials with control groups, and parallel groups,single blind, randomized ,phase 2 is on 40 patients.Software has been used for randomization

Settings and conduct

Patients who are candidates for orthopedic and spinal surgery at Sina Hospital in Tehran are randomly divided into two groups.This study is one blind , and patients are unaware of the type of intervention. following bleeding during surgery more than 500 ml and systolic blood pressure of less than 100 mmHg, the bicarbonate infusion is started at a rate of 5 cc /min in intervention group, blood transfusion began according to the results of blood gases and blood lactate levels. control group: Instead of bicarbonate, serum Ringer's infusion is started and blood transfusion is began according to the results of blood gases and blood lactate levels.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All patients with ASA I,II and III are candidates for orthopedic, neurosurgery, and vascular surgery. Their bleeding is more than 500 cc and after bleeding, they find a drop in blood pressure of less than 100 mm Hg and need a blood transfusion Exclusion Criteria: All patients with liver dysfunction, lung disorders such as COPD, and increased ICP

Intervention groups

Intervention group: In this group, by increasing bleeding and lowering blood pressure, bicarbonate infusion begins. ABG, blood lactate, and blood pressure tests are performed and blood transfusions are given according to their results. Control group: In this group, by increasing bleeding and lowering blood pressure, serum Ringer infusion begins. ABG, blood lactate, and blood pressure tests are performed and blood transfusions are given according to their results.

Main outcome variables

Blood pressure-Acidosis-Blood Lactate-

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N5**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**
Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of hemodynamic effects of bicarbonate infusion in hemorrhagic shock

Public title
The effect of bicarbonate in increasing blood pressure in patients with hemorrhagic shock
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients whose bleeding is more than 500 cc systolic blood pressure lower than 100 mm patients with ASA I,II,III who are candidates for orthopedic Hip surgery, neurosurgery, and vascular surgery. patients required to receive blood transfusions, patients with hemorrhagic shock
Exclusion criteria:
All patients with liver dysfunction lung disorders such as COPD increased ICP Patients who do not agree to participate in this study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **3**
Hip joint surgery has a lot of bleeding. The bicarbonate infusion raised blood pressure
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize patients with inclusion criteria Block balanced randomization is used.Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient is unaware of the type of intervention
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of ،Tehran University of Medical Sciences
Street address
SinaHospital, ImamKhomeini st.
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2019-06-11, 1398/03/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.213

Health conditions studied

1

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

2

Description of health condition studied
Acidosis
ICD-10 code
E87.2
ICD-10 code description
Acidosis

Primary outcomes

1

Description
Lactic Acidosis
Timepoint
At the end of surgery
Method of measurement
Vein blood sample mg/dl

2

Description
blood pressure changes
Timepoint
After the start of bicarbonate or serum at minutes 3-6-9

12-15

Method of measurement

Through the artier line with Lidco device /mmgh

Secondary outcomes

1

Description

blood acidosis

Timepoint

At the end of transfusion

Method of measurement

Arterial blood sample

Intervention groups

1

Description

Intervention group: Patients who has blood loss more than 500 cc during surgery within 20 minutes and have a systolic blood pressure less than 100 mm Hg, sodium bicarbonate infusion started at a rate of 5 cc / minute intravenously and continue until the systolic blood pressure reaches 100 mm Hg,then reduce the rate of bicarbonate to 2 cc/ minute.If the bleeding increases to the tolerable limit level , in each patient transfusion is started .At the end of the transfusion and stop the bleeding, a blood sample is sent to measure blood gases and lactic acid in the blood.

Category

Treatment - Drugs

2

Description

Control group: Patients who has blood loss more than 500 cc during surgery within 20 minutes and have a systolic blood pressure less than 100 mm Hg, Serum Ringer infusion starts at 15 ml / min. If the pressure does not rise after 10 minutes, the Nor adrenaline infusion begins.If the bleeding increases to the tolerable limit level in each patient, transfusion will start .At the end of the transfusion and stop the bleeding, a blood sample is sent to measure blood gases and lactic acid in the blood.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mohammad Reza Khajavi

Street address

Sina Hospital Hassan Abad sq, em mam khomini st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Khajavi

Position

Professor

Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Mohammad Reza Khajavi
Position
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Person responsible for updating data

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Email
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Web page address

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
Undecided - It is not yet known if there will be 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
All information used for this research can be shared after unidentified the identity of patients. Also, statistical information, information analysis, study method, findings and conclusions can be shared.
When the data will become available and for how long
Starting access after accepting by a valid scientific journal and publishing it
To whom data/document is available
For academic researchers and in the field of science
Under which criteria data/document could be used
All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.
From where data/document is obtainable
Dr. Mohammad Reza Khajavi Email: khajavim@tums.ac.ir
What processes are involved for a request to access data/document
The applicant can request the type of files by email.
Comments