Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of normal saline with Ringer's serum on Venus blood Gas (VBG(changes in inguinal hernia surgery patients under spinal anesthesia

Protocol summary

Study aim

"Determining and comparing the effect of normal saline and Ringer's serum on venous blood gas changes in inguinal hernia surgery patients under spinal anesthesia, in order to identify the most suitable fluid to improve clinical and hemodynamic results in these patients

Design

A double-blind clinical trial with 70 patients will be randomly divided into two groups of normal saline and Ringer's serum. The patient and the outcome assessor (researcher) will be unaware of the administered fluid.

Settings and conduct

Patients undergoing inguinal hernia surgery in Imam Khomeini Hospital, in NS group will receive 500 cc bolus before spinal anesthesia and 20 cc during surgery per kilogram of body weight only NS serum, and Ringer R group patients will receive 500 cc bolus before spinal anesthesia 500 cc bolus and during surgery 20 cc per kilogram of body weight will receive Ringer's only as crystalloid. And the patient and the outcome assessor (researcher) will be unaware of the administered fluid.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: age above 18 years and below 85 years 2- ASA I, II physical status and exclusion criteria for bilateral hernias 2- emergency inguinal hernia repair operations 3- kidney failure patients 4- patients with adrenal insufficiency and patients Suffering from heart and lung diseases.

Intervention groups

Patients will be randomly divided equally into one of two fluid therapy protocols with normal saline or Ringer's

Main outcome variables

Changes in venous blood gases, carbon dioxide pressure (pCO2), oxygen pressure (pO2), bicarbonate (HCO3-)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241108063640N1**
Registration date: **2024-11-13, 1403/08/23**
Registration timing: **prospective**

Last update: **2024-11-13, 1403/08/23**
Update count: **0**

Registration date

2024-11-13, 1403/08/23

Registrant information

Name

hadi Hooshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

hooshyarhadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-20, 1403/09/30

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of normal saline with Ringer's serum on Venus blood Gas (VBG(changes in inguinal hernia surgery patients under spinal anesthesia

Public title
Comparison of normal saline with Ringer's serum on Venus blood Gas (VBG(changes in inguinal hernia surgery patients under spinal anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years and under 85 years Physical status ASA I, II Patients undergoing inguinal hernia repair surgery

Exclusion criteria:
Bilateral hernias Emergency inguinal hernia repair operations Renal failure patients Adrenal failure patients patients with heart and lung diseases

Age
From **18 years** old to **85 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups A and B using Random Allocation computer software. By selecting the simple randomization method in the randomization method section and entering the total sample size determined in this software, numbers will be given to the patients and the patients will be entered into two groups based on the numbers given by the computer. Randomization will be done based on the permuted block randomization method. Each block will have 7 capacities. 5 blocks will be built based on the example of ABABABA, where in each block, people are evenly assigned to two groups. After that, in each block, people are randomly assigned to the normal saline group (A) (35 patients) or the Ringer's serum group (B) (35 patients). In this study, randomization will be simple, in a box, the number 1 to 70 will be written on sheets of paper and placed inside the box in an unspecified manner. One sheet will be removed for each disease, if the number is even. It will be placed in the first group, and if the number is odd, it will be in the second group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The method of blinding will be such that only the anesthesiologist will be aware of the serum being injected and the type of intraoperative fluids given will be hidden from the patients, surgeons and laboratory technicians involved in the study.

Placebo
Not used

Assignment
Parallel

Other design features
Determination and comparison of normal saline with Ringer's serum on venous blood gas changes in inguinal hernia surgery patients under spinal anesthesia

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Imam Khomeini Hospital

Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd

City
Urmia

Province
West Azarbaijan

Postal code
5715789397

Approval date
2024-10-22, 1403/08/01

Ethics committee reference number
IR.UMSU.HIMAM.REC.1403.080

Health conditions studied

1

Description of health condition studied
Inguinal hernia surgery patients under spinal anesthesia

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Assessment of changes in venous blood gases

Timepoint
After administration of normal saline and Ringer's serum

Method of measurement
Immediately at the end of the surgery, the blood sample will be collected again and will be sent to the laboratory to check sodium and potassium levels and venous blood gases.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the NS group will receive only NS serum before spinal anesthesia as a bolus of 500 cc and during surgery as a bolus of 20 cc per kilogram of body weight.
Category
Treatment - Drugs

2

Description
Intervention group: Ringer group R patients will receive 500 cc bolus before spinal anesthesia and 20 cc per kilogram of body weight as crystalloid only.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Urmia
Full name of responsible person
Dr.Hadi Hooshyar
Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715789397
Phone
+98 44 3346 9931
Fax
+98 44 3345 7277
Email
hooshyarhadi@gmail.com
Web page address
http://Imam.umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Resalat Boulevard - Emergency Alley - Urmia University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
5718748983
Phone
+98 44 3237 5907
Email
sabergholizadeh@yahoo.com
Web page address
http://umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Hadi Hooshyar
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715789397
Phone
+98 44 3346 9931
Email
hooshyarhadi@gmail.com
Web page address
http://Imam.umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr.Hadi Hooshyar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Postal code
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Phone
+98 44 3346 9931

Email
hooshyarhadi@gmail.com

Web page address
http://Imam.umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr.Hadi Hooshyar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia

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Phone
+98 44 3346 9931

Fax
+98 44 3345 7277

Email
hooshyarhadi@gmail.com

Web page address
http://Imam.umsu.ac.ir

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