Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of preloading with normal saline solution and voluven on the spread of sensory block with hyperbaric bupivacaine after spinal anesthesia

Protocol summary

Summary

The overall objective of the project: determination of the effect of preloading with normal saline and Voluven on the distribution of block with hyperbaric bupivacaine for spinal anesthesia study design: randomized, double-blind study population: all patients 20 to 70years, scheduled for lower abdominal surgery that can be done With spinal anesthesia Inclusion criteria: a) all patients 20 to 70 years, scheduled for lower abdominal surgery with spinal anesthesia B) ASA I-II - Non-inclusion criteria: a) the inability to collaborate and determine the level of anesthesia by patients, b) patients with Spinal disorderand deformity d) contraindications to spinal anesthesia e) contraindications for use of voluven a) lack of consent and cooperation of the patient) patients needing transfusion or infusion of additional fluids during surgery due to hemodynamic instability sample size: 60 Intervention: Selected patients will be divided into two equal groups of 30. Patients randomized, double-blind fall into one of two groups. The first group of 10 to 15 minutes before spinal anesthesia 10ml / kg of saline solution and a second group 5ml / kg Voluven solution within 10 to 15 minutes will receive. Intervention time: before spinal anesthesia outcomes: the level of block

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121616956N7**
Registration date: **2016-06-27, 1395/04/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Hassan Mohammadipour Anvari

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of preloading with normal saline solution and voluven on the spread of sensory block with hyperbaric bupivacaine after spinal anesthesia

Public title

Compare the effect of preloading in spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients 20 to 70 years, scheduled

for lower abdominal surgery with spinal anesthesia: ASA I-II Excinclusion criteria: the inability to collaborate and determine the level of anesthesia by patients: patients with Spinal disorder and deformity: contraindications to spinal anesthesia: contraindications for use of voluven: lack of consent and cooperation of the patient: patients needing transfusion or infusion of additional fluids during surgery due to hemodynamic instability

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Using random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of tabriz University of Medical Sciences

Street address
Tabriz, golgasht street, Tabriz University of Medical Sciences, Central Building 2, third floor, Department of Research and Technology

City
tabriz

Postal code

Approval date
2015-10-12, 1394/07/20

Ethics committee reference number
TBZMED.REC.1394.678

Health conditions studied

1

Description of health condition studied
The effect of pretreatment with various solutions at the level of sensory block in the spinal anesthesia

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Sensory block level

Timepoint
Every 5 minutes to 30 minutes and then 60 minutes after spinal anesthesia and 90

Method of measurement
pinprick test

Secondary outcomes

1

Description
Headache

Timepoint
Postoperative

Method of measurement
Ask the patient

2

Description
blood pressure

Timepoint
Every 5 minutes to 30 minutes and then every 15 minutes until the end of surgery

Method of measurement
By monitoring

3

Description
Heart rate

Timepoint
Every 5 minutes to 30 minutes and then every 15 minutes until the end of surgery

Method of measurement
By monitoring

Intervention groups

1

Description
Intervention group 1: 10 to 15 minutes before spinal anesthesia 10ml / kg normal saline within 10 to 15 minutes will receive

Category
Prevention

2

Description
Intervention group 2: 10 to 15 minutes before spinal anesthesia 5ml / kg voluven within 10 to 15 minutes will receive.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
doctor Hassan Mohammad Pour Anvari
Street address
tabriz.golgasht street
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,tabriz University of Medical Sciences
Full name of responsible person
soleimanpour dr.
Street address
Golgasht Street.medical school
City
tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Email
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty