

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 disorder and 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

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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 Exclusion 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

tabriz University of Medical Sciences

Full name of responsible person

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Position

Professor of Anesthesiology

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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