

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the Effect of Four Different Doses of Intrathecal Isobaric Ropivacaine on Patients Undergoing Elective Infra-umbilical Surgeries

Protocol summary

Study aim

Determining the appropriate dose of Ropivacaine in umbilical cord surgery, reducing the failure rate and minimizing the side effects of spinal block

Design

Clinical trial with 4 intervention groups, double-blind, randomized, phase 2 on 140 patients. Random block allocation with 8 blocks is used for randomization.

Settings and conduct

The study site was located in Shahid Beheshti Hospital located in Qom. As a random selection of patients in need of umbilical cord surgery, the 8-block method is used for placement in intervention groups. Two-way blinding including data recorder and data analyzer .

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient is over 18 years old, has a broken arm and needs surgery, and has American Stroke Association level 1 or 2. Exclusion criteria: The patient is addicted to drugs, is pregnant, non-Iranian race, is not satisfied to enter this study.

Intervention groups

Intervention group 1: Patients for spinal anesthesia receive 4 ml of Ropivacaine 0.5% equivalent to 20 mg. Intervention group 2: Patients for spinal anesthesia receive 4.5 ml of 0.5% Ropivacaine equivalent to 22.5 mg. Intervention group 3: Patients for spinal anesthesia receive 5 ml of Ropivacaine 0.5% equivalent to 25 mg. Intervention group 4: Patients receive 5.5 ml of Ropivacaine equal to 27.5 mg for spinal anesthesia.

Main outcome variables

The quality of anesthesia for the patient in terms of comfort during the operation and the need for painkillers after surgery; The length of stay of patients in the recovery department after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211017052786N4**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Amir Hossein Moradi Rafigh

Name of organization / entity

Qom university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 25 3885 6440

Email address

amirmmr287@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Four Different Doses of Intrathecal Isobaric Ropivacaine on Patients Undergoing Elective Infra-umbilical Surgeries

Public title

Comparison of the effect of different doses of intrathecal Ropivacaine in surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian race Patients with American Stroke Association (ASA) grade 1, 2 Umbilical cord surgeries Age over 18 and under 65 years

Exclusion criteria:

Allergy to amide drugs Pregnancy History of substance abuse Heart rate less than 60 beats per minute at rest

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 140 patients undergoing umbilical cord surgery will be randomly divided into four groups of 35 patients. Random assignment of patients to four groups is based on block method. Each block will be selected at random. Block Randomization is done using dice.

Throwing the dice will be done enough to complete the assignment of patients to treatment groups. The size of the block is 8 and we will have different and random combinations of AABBCDD. The selection of each block will be random to complete the allocation of patients to treatment groups with four different doses. Assignment of treatment to groups A, B, C and D will also be based on accident.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind randomized clinical trial (RCT) in which the participating patients, specialist assistant and surgeon do not know the type of dose assignment to the group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of QOM University of Medical Sciences

Street address

No.10, 13th Ave., Emam Street.

City

Qom

Province

Ghoum

Postal code

3718913997

Approval date

2022-06-19, 1401/03/29

Ethics committee reference number

IR.MUQ.REC.1401.064

Health conditions studied

1

Description of health condition studied

Spinal anesthesia using ropivacaine

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Levels of sensory and motor block

Timepoint

In minutes 15,10,8,8,6,4,2

Method of measurement

Motor nerves using voice commands for the patient and Pinprick of skin to observe the sensory nerve response

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Candidate patients for below-umbilical surgery for spinal anesthesia receive 4 ml of 0.5% Ropivacaine with chemical formula (C17H26N2O) equivalent to 20 mg intra-cerebrospinal fluid (CSF).

Category

Treatment - Other

2

Description

Intervention group 2: Candidate patients for below-umbilical surgery for spinal anesthesia receive 4.5 ml of Ropivacaine 0.5% with chemical formula (C17H26N2O) equivalent to 22.5 mg intra-cerebrospinal fluid (CSF).

Category

Treatment - Other

3

Description

Intervention group 3: Candidate patients for below-umbilical surgery for spinal anesthesia receive 5 ml of 0.5% Ropivacaine with chemical formula (C17H26N2O) equivalent to 25 mg intra-cerebrospinal fluid (CSF).

Category

Treatment - Other

4

Description

Intervention group 4: Candidate patients for below-umbilical surgery for spinal anesthesia receive 5.5 ml of Ropivacaine 0.5% with chemical formula (C17H26N2O) equivalent to 27.5 mg intra-cerebrospinal fluid (CSF)..

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Hamed Shafiee

Street address

Shahid Beheshti Blvd

City

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Ghous

Postal code

3719964797

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Email

Bmc@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Vahid Damanpak

Street address

No. 83, Forth Ave., Safa Shahr Street

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3716987366

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Amirmmr287@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Amir Hossein Moradi Rafigh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Amirmmr287@gamil.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Fatemeh Gghannadi

Position

Residnet

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Web page address**Other areas of specialty/work**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to the present study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Amir Hossein Moradi Rafigh

Position

Student

Latest degree

A Level or less