

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the Effect of Spinal Anesthesia with Ropivacaine and Marcain on Cesarean Section in Preeclampsia Patients

Protocol summary

Study aim

Comparison of the effect of spinal anesthesia with ropivacaine and marcaine in cesarean section of preeclamptic patients

Design

Clinical trial with two parallel, double-blind, randomized groups on 90 patients. Lottery was used for randomization.

Settings and conduct

This study will be performed in Shahid Bahonar Hospital in Kerman. Colleagues who measure hemodynamic and pain indices in the operating room and ward, as well as a statistical analyst, will be unaware of the grouping.

Participants/Inclusion and exclusion criteria

Pregnant women with preeclampsia are candidates for cesarean section

Intervention groups

Intervention 1: Spinal anesthesia with ropivacaine
Intervention 2: Spinal anesthesia with marcain

Main outcome variables

The required dose of ephedrine; Duration of movement block; State of painlessness; blood pressure; Heart rate; Duration of onset of motor block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150317021497N6**
Registration date: **2021-05-09, 1400/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-09, 1400/02/19**

Update count: **0**

Registration date

2021-05-09, 1400/02/19

Registrant information

Name

Mohammadreza Mokhtaree

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34260081

Email address

mrmmokhtaree@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-03, 1400/02/13

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Spinal Anesthesia with Ropivacaine and Marcain on Cesarean Section in Preeclampsia Patients

Public title

Comparison of Ropivacaine and Marcain on Cesarean Section in Preeclampsia Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with preeclampsia Satisfaction with spinal anesthesia Absence of thrombocytopenia (PLT <70000) with coagulation disorder Absence of spinal

infection

Exclusion criteria:

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block assignment to two groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Colleagues who measured hemodynamic and pain indices in the operating room and ward, as well as a statistical analyst, were unaware of the grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Qarni St., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Approval date

2019-12-05, 1398/09/14

Ethics committee reference number

IR.KMU.AH.REC.1398.151

Health conditions studied

1

Description of health condition studied

Hemodynamic indices, duration of motor block onset,

duration of motor block, required dose of ephedrine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemodynamic indices, duration of motor block onset, duration of motor block, required dose of ephedrine

Timepoint

Before anesthesia, after anesthesia in 2, 4, 6, 8, 10, 15, 20, 25, 30, 35 minutes

Method of measurement

Checklist, monitoring device, mercury barometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Spinal anesthesia with ropivacaine

Category

Treatment - Drugs

2

Description

Intervention group: Spinal anesthesia with marcaine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Abbas Pardakhty

Street address

Somayeh intersection (Tahmasb Abad) at the beginning of Ibn Sina Street

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

abpardakhty@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Somayeh intersection (Tahmasb Abad) at the beginning of Ibn Sina Street

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

abpardakhty@kmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Leila Rezaeizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Qarni St., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

l.rezaizadeh@kmu.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Leila Rezaeizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Qarni St., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

l.rezaizadeh@kmu.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Leila Rezaeizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Qarni St., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

l.rezaizadeh@kmu.ac.ir

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

Yes - There is 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 data is potentially shareable after unidentified individuals

When the data will become available and for how long

6 months from the end of the study

To whom data/document is available

Only researchers working in academic and scientific institutions

Under which criteria data/document could be used

Information is provided only by letter from the scientific and academic institute.

From where data/document is obtainable

Leila Rezaeizadeh, 09131782131

What processes are involved for a request to access data/document

After submitting the official letter, the permit is issued by the Deputy Minister of Research.

Comments