# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of co-administration of oral pregabalin and intravenous ketorolac on post-operative pain in patients undergoing cesarean section with spinal anesthesia.

## Protocol summary

**Study aim**
Evaluation of the effect of concomitant oral administration of pregabalin and intravenous ketorolac on postoperative pain in patients undergoing spinal sensory cesarean section

**Design**
A clinical trial with a control group, with parallel groups, without blinding, with random allocation using the table of random numbers, phase 3 on 56 patients.

**Settings and conduct**
One hour before the operation, patients in the intervention group received one 150 mg oral pregabalin capsule and a dose of 30 mg intravenous ketorolac and in the control group, patients received placebo. After 15 minutes, the patient is placed in a sitting position and received 2.5 cc of bupivacaine hyperbaric via spinal cord with needle No. 25 after the CSF is expelled. Intravenous ringer lactate 15 cc/kg/h is prescribed until the end of surgery. After the fetus delivered, 10 units of oxytocin are slowly infused into one liter of serum. Postoperatively, patients' pain will be assessed at three-times (6, 12, and 24 hours) using a VAS scale. Study place: Imam Reza hospital and Ghaem hospital in Mashhad.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Pregnant mothers with I ASA and 18-40 years old candidates for elective cesarean section and spinal anesthesia and have no history of any neurological disease, calcium channel blocker, and analgesia in the last 3 months. Exclusion criteria: the need for general anesthesia for any reason, contraindications to spinal surgery, and people who have a contraindication for pregabalin use.

**Intervention groups**
Intervention group: This group receives a 150 mg capsule of pregabalin and a dose of 30 mg ketorolac intravenously one hour before surgery. Control group: This group receives one placebo capsule with a 30 mg intravenous dosage block 1 hour before surgery.

**Main outcome variables**
Pain (VAS)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220114053711N1**
Registration date: **2022-08-26, 1401/06/04**
Registration timing: **prospective**

Last update: **2022-08-26, 1401/06/04**
Update count: **0**

**Registration date**
2022-08-26, 1401/06/04

**Registrant information**

**Name**
seyed majid taghizadeh mayani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3800 2000

**Email address**
taghizadehm3@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-12-06, 1401/09/15

**Expected recruitment end date**
2023-03-06, 1401/12/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of co-administration of oral pregabalin and intravenous ketorolac on post-operative pain in patients undergoing cesarean section with spinal anesthesia.

**Public title**

Effect of co-administration of oral pregabalin and intravenous ketorolac on post-operative pain in patients undergoing cesarean section with spinal anesthesia.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Pregnant mothers with I ASA and 18-40 years old who are candidates for elective cesarean section and spinal anesthesia, sign the informed consent form to participate in this project. Do not have a history of any neurological disease in the last three months. There are no contraindications to spinal surgery (hemodynamic abnormalities, coagulation defects, history of allergy to local anesthetics, lack of patient cooperation, and local infection). Do not have a history of taking calcium channel blockers and painkillers in the last three months.

**Exclusion criteria:**

Need general anesthesia for any reason People with a contraindication for pregabalin use (a history of previous allergies to pregabalin or any of the ingredients in its formulation). Community Verified icon

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling method is available and patients are divided into two groups of intervention (n = 28) and placebo (n = 28) based on random allocation method (with table of random numbers). The assigned codes are written separately on separate sheets and placed in separate envelopes or updated in such a way that the code written inside them is not available. After each patient with inclusion criteria is referred, an envelope is removed in order and according to the code written in it (for example a / b) the patient is placed in one of two groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Danesh and Salamat Shahrek, between Shahidjovan and Al Shahidi Square, Shaheed Fakuri Blvd, Mashhad, Khorasan Razavi

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2022-06-13, 1401/03/23

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.172

## Health conditions studied

**1**

**Description of health condition studied**

cesarean section

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

**1**

**Description**

Postoperative pain

**Timepoint**

at 6, 12, and 24 hours after surgery

**Method of measurement**

VAS (visual analog scale)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: This group receives a 150 mg capsule of pregabalin one hour before the operation and

a 30 mg dose of intravenous ketorolac during the operation after clamping the Tuff band.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: The control group receives a placebo one hour before the operation.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza hospital of Mashhad

**Full name of responsible person**

Seyyed Majid Taghizadeh Mayani

**Street address**

Imam Reza Research and Treatment Center, Imam Reza Hospital Square, Ibn Sina St, Mashhad, Khorasan Razavi

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

+989137913316

**Phone**

+98 51 3854 3031

**Email**

presidentoffice@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayor Mobarhan

**Street address**

Mashhad, University Street, University of Medical Sciences, University Research and Technology Vice-Chancellor, 3rd floor

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Email**

vcresraech@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Majid Taghizadeh Mayani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Mashhad Central Medical Sciences Building, University Street.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3800 2000

**Fax**

**Email**

taghizadehm3@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Majid Taghizadeh Mayani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Phone**
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**Fax**
**Email**
taghizadehm3@mums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Seyed Majid Taghizadeh Mayani
**Position**
Resident
**Latest degree**
Medical doctor
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Anesthesiology
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Mashhad Central Medical Sciences Building, University Street.
**City**
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## 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 de-identifying individuals.
**When the data will become available and for how long**
The access period starts 6 months after the results are published.
**To whom data/document is available**
The data will be available only to researchers working in academic and scientific institutions.
**Under which criteria data/document could be used**
The data can only be requested by academic and scientific researchers and after providing documentation indicating their employment and providing documentation indicating the reason for requesting the data.
**From where data/document is obtainable**
Central Organization of Mashhad University of Medical Sciences, number: 051 38049
**What processes are involved for a request to access data/document**
After the request from Mashhad University of Medical Sciences, the review will be done in about three months.
**Comments**