Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of prophylactic administration of Quetiapine and Diclofenac sodium on pain relief after major lower limb and pelvic surgeries under spinal anesthesia

Protocol summary

Study aim

The effect of Quetiapine and Diclofenac sodium on pain after major lower limb and pelvic surgeries

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 105 patients. Randomization is done in a simple way by lottery.

Settings and conduct

This clinical trial will be performed on 105 patients who are candidates for major lower limb and pelvic surgery at Alzahra Hospital in Isfahan. After the approval of the ethics committee and obtaining written consent from the patients, in each group, the patients receive the intervention related to that group 30 minutes before the operation. After entering the operating room, they are fully monitored and after receiving Midazolam and Fentanyl as a premedication, spinal anesthesia is performed by standard methods. After the operation, clinical symptoms and Surgical complications will also be recorded in the patient. The severity of the patient's pain is also measured and recorded according to the VAS criteria. The person who records the patient's symptoms is different from the researcher injecting the drug and is unaware of the type of intervention. The patient is also unaware of the type of intervention and is therefore blind.

Participants/Inclusion and exclusion criteria

All patients aged 18 to 65 years who are candidates for major lower limb and pelvic surgery under spinal anesthesia can enter the study if they do not have a specific underlying disease and do not take drugs that interfere with the study interventions.

Intervention groups

Intervention group A: In this group, patients receive 50 mg of oral Quetiapine 30 minutes before surgery.
Intervention group B: In this group, patients receive 100 mg of oral Diclofenac sodium 30 minutes before surgery.
Intervention group C: In this group, patients receive a placebo 30 minutes before the operation.

Main outcome variables

The amount of pain after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N36**
Registration date: **2021-10-14, 1400/07/22**
Registration timing: **prospective**

Last update: **2021-10-14, 1400/07/22**
Update count: **0**

Registration date

2021-10-14, 1400/07/22

Registrant information

Name
Behzad Nazemroaya
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 31 3212 3543
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behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of prophylactic administration of Quetiapine and Diclofenac sodium on pain relief after major lower limb and pelvic surgeries under spinal anesthesia

Public title
Evaluation of the effect of Quetiapine and Diclofenac in reducing pain in lower limb surgeries
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 64 years ASA Class I and II Anesthesia Candidate for major lower limb and pelvic surgeries Candidate for spinal anesthesia Patient informed consent to participate in the study
Exclusion criteria:
Taking psychotropic or sedative drugs Opioid and non-opioid drug addiction Diabetes, orthostatic hypotension, bradycardia, hypokalemia, hypothyroidism, depression, dementia, prolonged QT syndrome Pregnancy and lactation Obesity (BMI>30)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a simple randomized clinical trial in which individuals enter study groups by lottery; The drugs and placebo are placed in the desired number in sealed opaque and uniform sealed envelopes. Each of the codes is also written on a piece of paper, folded and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box. Which is applied to the patient. This continues until the end of the paperwork so that the number of patients in the desired volume in the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a two-blind study, patients are explained that during the study they are placed in one of the groups by lottery, but the type of intervention is not known in advance, so the patient is unaware of the type of intervention despite the conscious participation in the study and is therefore blind. Medications are also prescribed by a researcher who is not involved in evaluating the patient and analyzing the results. An anesthesiologist who is in charge of anesthesia management and data collection during and after surgery, as well as the researcher who evaluates and analyzes the results, will not know the type of drug prescribed and therefore are all blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
Street address
Hezar Jarib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-05-22, 1400/03/01
Ethics committee reference number
IR.MUI.MED.REC.1400.366

Health conditions studied

1

Description of health condition studied
Amount of post operation pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The severity of postoperative pain
Timepoint
Base time (before intervention), awakening, 1, 2, 4, 6 and 24 hours after surgery
Method of measurement

Visual Analogue Scale (0 to 10)

Secondary outcomes

1

Description
Moderate arterial blood pressure
Timepoint
Base time (before intervention), awakening, 1, 2, 4, 6 and 24 hours after surgery
Method of measurement
Barometer

2

Description
Heart Rate
Timepoint
Base time (before intervention), awakening, 1, 2, 4, 6 and 24 hours after surgery
Method of measurement
ECG

3

Description
Arterial blood oxygen saturation
Timepoint
Base time (before intervention), awakening, 1, 2, 4, 6 and 24 hours after surgery
Method of measurement
Pulse oximeter

4

Description
Complications (such as nausea, vomiting, dizziness, drowsiness, headache)
Timepoint
Base time (before intervention), awakening, 1, 2, 4, 6 and 24 hours after surgery
Method of measurement
Asking

Intervention groups

1

Description
Intervention group A: In this group, patients who have not eaten for at least 8 hours before the operation receive 50 mg of oral Quitiapine 30 minutes before induction of anesthesia and then undergo standard monitoring. 0.03 mg / kg Midazolam and 2 µg / kg Fentanyl are injected intravenously as a premedication , then the patient is placed under spinal anesthesia.
Category
Prevention

2

Description
Intervention group B: In this group, patients who have not eaten for at least 8 hours before the operation receive100 mg of oral Diclofenac 30 minutes before induction of anesthesia and then undergo standard monitoring. 0.03 mg / kg Midazolam and 2 µg / kg Fentanyl are injected intravenously as a premedication , then the patient is placed under spinal anesthesia.
Category
Prevention

3

Description
Control group C: In this group, patients who have not eaten for at least 8 hours before the operation receive One placebo pill 30 minutes before induction of anesthesia and then undergo standard monitoring. 0.03 mg / kg Midazolam and 2 µg / kg Fentanyl are injected intravenously as a premedication , then the patient is placed under spinal anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad Nazemoroaya
Street address
Soffeh boulevard, Shahid Keshvari highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Azadeh Erfani
Position
Assistant to anesthesia and intensive care
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available