

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the efficacy of Pregabalin with Duloxetine in perioperative pain management in knee fractures surgery: A randomized, double-blind, clinical trial

Protocol summary

Study aim

comparing the effectiveness and effect on reducing opioid consumption and between Pregabalin and Duloxetine as part of a multi-modal analgesia regimen to manage pain orthopedic surgery

Design

Clinical trial, two parallel intervention groups, double-blind, randomized, phase 2 on 68 patients. Block randomization method is used.

Settings and conduct

Patients who are admitted to Sina Hospital following fractures around the knee and placed on the operation list for surgery, after obtaining informed consent from them or their legal guardians, will be included. with block randomisation method, patients will be divided into two groups and they receive either capsules containing 75 mg Pregabalin or 30 mg Duloxetine every 12 hours at least 24 hours before surgery until 48h after it. Along with each of these drugs, all patients will similarly receive other analgesics according to hospital protocol. The intensity of the patient's pain at the beginning of the study, immediately before surgery and 6, 12, 24 and 48 hours after it will be evaluated and recorded using a numeric rating scale from 0 to 10. In case of pain intensity greater than 6, intramuscular Morphine will be administered at a dose of 0.05 mg/kg (maximum 4 mg) with a maximum frequency of every 4 hours. The patient will be followed up within 48 hours after the surgery for cumulative opioid consumption and side effects related to the drugs.

Participants/Inclusion and exclusion criteria

Inclusion: age 18 to 80 years /Exclusion: History of taking or allergy to study drugs, dependence to opioid or use within 24 hours before entering the study, Use of epidural anesthesia in surgery

Intervention groups

One group will receive an oral capsule containing

Pregabalin and another will receive an oral capsule containing Duloxetine (all capsules looks similar).

Main outcome variables

pain intensity score; Cumulative dose of opioid consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230416057923N1**

Registration date: **2023-05-16, 1402/02/26**

Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**

Update count: **0**

Registration date

2023-05-16, 1402/02/26

Registrant information

Name

Mohadeseh Masoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Pregabalin with Duloxetine in perioperative pain management in knee fractures surgery: A randomized, double-blind, clinical trial

Public title

Comparing the efficacy of Pregabalin with Duloxetine in perioperative pain management in knee fractures surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 80 years Patients with fractures around the knee who are hospitalized and undergo surgery The patient is willing to participate in the study and sign the informed consent form.

Exclusion criteria:

History of taking Duloxetine, Pregabalin and Gabapentin within two weeks before surgery History of allergy to study drugs Severe active infection leads to cognitive impairment Severe renal failure (MDRD renal clearance less than 30 ml/min/1.73m²) Severe liver failure (Child Pugh C or liver enzymes more than 5 times the maximum normal range) Moderate to severe dependence (according to DSM5 criteria) to opioids or use within 24 hours before entering the study BMI greater than or equal to 40 kg/m² ASA Physical status IV/V Use of epidural anesthesia in surgery Pregnancy and breastfeeding NPO patients Active gastrointestinal ulcer high risk of bleeding before or after surgery Participate in another trial at the same time Concomitant use of SNRI, TCA, MAOI, St John wort within two weeks before entering the study Hemodynamic instability Being a communication barrier with the patient to evaluate him

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple block randomization: Patients will be divided into two groups by block randomization of 4 and 6 numbers. The random sequence will be created using the site

<https://www.sealedenvelope.com/simple-randomiser/v1/li>. Concealment will also be done using The block randomization method is guaranteed. Packs of 8 capsules containing Duloxetine and Pregabalin, which are completely similar, are coded and provided to the researcher by a person who is not involved in the treatment, patient monitoring and analysis given in the study. The codes will be kept with this person until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

We will have two types of capsules A and B that are completely similar in terms of appearance, which are coded and prepared by someone other than the researchers and the patient, and he knows which type of capsule contains which of the study drugs, and the researcher who interviews the patients and the patients do not know which one Pregabalin or Duloxetine is prescribed for each patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institute of Pharmaceutical Sciences of Tehran
University of Medical Sciences (Research Ethics
Comm

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Faculty of Pharmacy, Tehran University of Medical
Sciences, poorsina Ave

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Province

Tehran

Postal code

14176-13151

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.008

Health conditions studied**1****Description of health condition studied**

perioperative pain in knee fractures surgery (patella)

ICD-10 code

S82.0

ICD-10 code description

Fracture of patella

2

Description of health condition studied

perioperative pain in knee fractures surgery (upper end of tibia)

ICD-10 code

S82.1

ICD-10 code description

Fracture of upper end of tibia

3

Description of health condition studied

perioperative pain in knee fractures surgery (lower end of femur)

ICD-10 code

S72.4

ICD-10 code description

Fracture of lower end of femur

Primary outcomes

1

Description

Pain intensity score

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and 6, 12, 24 and 48 hours after the operation.

Method of measurement

Asking the patient with a numerical rating scale (NRS) (0 to 10)

2

Description

Cumulative dose of opioid consumption

Timepoint

48 hours after the operation

Method of measurement

Record the cumulative amount of opioid consumed (using the patient file report) in the period from the beginning of the study to 48 hours after the operation.

3

Description

The time of the patient's first need for opioids

Timepoint

During 48 hours after the operation

Method of measurement

The time recorded in the patient's record report

Secondary outcomes

1

Description

Nausea or vomiting

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and then during the 48 hours after the operation.

Method of measurement

Visiting and asking the patient

2

Description

hypoxia, Oxygen saturation (spo2) less than 89% on ambient air

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and then during the 48 hours after the operation.

Method of measurement

View the Oxygen saturation (SpO2) values recorded in each visit from the patient's file

3

Description

Bradycardia, Heart rate number less than 60 beats/min

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and then during the 48 hours after the operation.

Method of measurement

Viewing the heart rate values recorded in each visit from the patient file

4

Description

Hypotension, Systolic blood pressure less than 60.90 mmHg that causes symptoms in the patient.

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and then during the 48 hours after the operation.

Method of measurement

View blood pressure values recorded in each visit from the patient file

5

Description

Occurrence or non-occurrence of delirium according to confusion assessment method for the ICU (CAM-ICU)

Timepoint

At the beginning of the study (before the start of the intervention), immediately before the operation and then during the 48 hours after the operation.

Method of measurement

confusion Assessment Method for the ICU (CAM-ICU) method in each visit

Intervention groups

1

Description

The first intervention group: a group of patients, from at least 24 hours before (at least two doses) until 48 hours after the operation, every 12 hours, an oral capsule containing 75 mg of Pregabalin (which is similar in appearance to the capsule of the other group) will do In addition, patients will similarly receive other analgesics according to hospital protocol

Category

Treatment - Drugs

2**Description**

The second intervention group: a group of patients, from at least 24 hours before (at least two doses) to 48 hours after the operation, every 12 hours, received an oral capsule containing 30 mg of Duloxetine (which is similar in appearance to the capsule of the other group). will do In addition, all patients will similarly receive other analgesics according to hospital protocol.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Farhad Najmeddin

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Sina Hospital, before reaching Hassan Abad Square, Imam Khomeini St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mohadeseh Masoumi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Clinical pharmacy

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farhad Najmeddin

Position

assistant professor

Latest degree

Subspecialist

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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

No - There is not 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

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**

Tehran University of Medical Sciences

Full name of responsible person

Mohadeseh Masoumi

Position

Resident

Latest degree