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 eather 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 surgary 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)

Phone

+98 21 6653 7764

Email address

masoumimohadese@gmail.com

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
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target 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 Commi
Street address
Faculty of Pharmacy, Tehran University of Medical Sciences, poorsina Ave
City
Tehran
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

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

City
Tehran

Province
Tehran

Postal code
۱۱۳۶۷۴۶۹۱۱

Phone
+98 21 6312 0000

Fax
+98 21 6634 8587

Email
hosp_sina@sina.tums.ac.ir

Web page address
https://sinahos.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotouhi

Street address
Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 81631

Email
tumspr@tums.ac.ir

Web page address
https://tums.ac.ir/

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

Street address
clinical pharmacy department, school of pharmacy 16th azar st.

City
Tehran

Province
Tehran

Postal code
1417614411

Phone
+98 21 6695 4709

Email
Masoumimohadese@gmail.com

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
Other areas of specialty/work
Clinical pharmacy
Street address
clinical pharmacy department, school of pharmacy
16th azar st.
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 4709
Email
f-najmeddin@sina.tums.ac.ir
Web page address
https://isid.research.ac.ir/Farhad_Najmeddin

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
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
clinical pharmacy department, school of pharmacy
16th azar st.
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 4709
Email
Masoumimohadese@gmail.com

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