Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the effectiveness of oral prescription of Oxycodone in comparison with standard analgesic treatment on postoperative pain and final function after knee replacement surgery

Protocol summary

Study aim

Determining the effect of oral oxycodone for four weeks after surgery on pain and function of patients after primary knee replacement.

Design

Randomized (by sealdenvelope.com) controlled clinical trial, parallel groups, triple-blind, in phase II on 2 groups of 95 patients underwent complete knee replacement.

Settings and conduct

Patients undergoing complete knee replacement surgery at Imam Khomeini Hospital in Tehran were randomly divided into 2 groups of 95 (placebo and oxycodone) and the patient, physician and nurse were triple blinded not being aware of the prescribed drug by categorizing drug coding by another person not related to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with knee osteoarthritis undergone total knee replacement Exclusion criteria: Drug and alcohol use, use of any other analgesics and antidepressants, and anti-epilepsy, previous history of surgery on the affected knee, intraoperative fracture, unwillingness of the patient to cooperate or continue follow-up, and bmi above 40 and Less than 20

Intervention groups

a triple-blind clinical trial in two groups of patients with knee osteoarthritis who underwent primary knee replacement surgery received standard analgesic therapy celecoxib (200 mg twice daily), acetaminophen (500 mg every 6 hours), and pregabalin (75 mg twice daily) from the time of surgery until discharge. After discharge, acetaminophen and celecoxib will be continued as needed for up to one month. Placebo is prescribed to the control group and oral oxycodone (5 mg) to the case group every 12 hours for four weeks.

Main outcome variables

knee pain, knee function, sleep quality, satisfaction, hospital length of stay

General information

Reason for update

The study protocol has been updated due to modifications in the study implementation method. The purpose of this update is to formally and accurately document the newly revised details related to the study design and execution. These revisions have been made with the aim of enhancing scientific accuracy, aligning with practical conditions, and improving the overall quality of the study.

Acronym

Faroxy TKA Trial

IRCT registration information

IRCT registration number: **IRCT20220413054520N1**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2025-07-18, 1404/04/27**
Update count: **2**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name
Seyyed Hadi Kalantar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

2023-07-01, 1402/04/10

Actual recruitment end date

2024-07-01, 1403/04/11

Trial completion date

2025-01-25, 1403/11/06

Scientific title

Evaluation of the effectiveness of oral prescription of Oxycodone in comparison with standard analgesic treatment on postoperative pain and final function after knee replacement surgery

Public title

Effect of One-Month Oral Oxycodone on Postoperative Pain and Functional Recovery Following Total Knee Arthroplasty: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of knee osteoarthritis requiring surgical intervention. Undergo primary total knee arthroplasty. Willingness and ability to provide informed consent. Commitment to comply with the study protocol and complete follow-up.

Exclusion criteria:

Current use of antidepressants or antiepileptic drugs. History of previous surgery on the affected knee. Patients who were involved in this trial for their previous knee (bilateral TKAs), and/or participation in other clinical trials Body Mass Index (BMI) > 40 or < 20. Regular alcohol consumption. Use of any analgesics not prescribed in the study protocol. Known hypersensitivity or contraindication to oxycodone or any other medications in the standard analgesic regimen. Severe hepatic or renal impairment (e.g., serum creatinine > 2.0 mg/dL, liver enzymes > 3 times the upper limit of normal). Active infection or ongoing inflammatory conditions affecting the knee joint. Psychiatric or cognitive conditions impairing the ability to comply with the study protocol. Pregnancy or lactation. Reluctance to cooperate or continue with follow-up.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **190**

Actual sample size reached: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized in a 1:1 ratio to receive either oxycodone or placebo. The study will be conducted in a triple-blind manner to ensure unbiased administration and assessment. Once a patient has been deemed eligible and has provided written informed consent, randomization will be performed using the Sealedenvelope.com platform. To maintain the integrity of the triple-blind design, the randomization process will be conducted by a designated nurse who has no involvement in the study. The randomization procedure involves assigning each patient a unique number, which is entered into the website. The website then allocates a randomized code corresponding to a pre-labeled box containing either oxycodone or placebo. Each box is pre-assigned a code by the software, and only the designated, uninvolved individual has access to the key that links codes to their respective contents. Patients will receive the study medication box corresponding to their assigned number.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This trial will be conducted as a triple-blind study. Study drugs will be coded into two categories (placebo and oxycodone) by an independent third party with no involvement in the study. Randomization will be performed using software to allocate treatment to patients without human intervention. Each participant will receive a numbered drug box, prepared according to the randomization software, containing either placebo or the active drug. Neither the patient, nurse, nor treating physician will be aware of the drug allocation (placebo or active drug) during the study. Additionally, the statistical analyst will also be blinded. The treatment code will remain concealed until the data analysis is completed. Unblinding will only occur in cases of medical necessity or at the conclusion of the study, ensuring the integrity of the trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran university of medical science, Keshavarz Blvrd, Tehran,Tehran,iran

City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2021-10-29, 1400/08/07
Ethics committee reference number
IR.TUMS.IKHC.REC.1400.177

Health conditions studied

1

Description of health condition studied
Knee replacement surgery
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Patient's knee pain
Timepoint
1, 7, and 30 days post-surgery
Method of measurement
Visual Analogue Scale score

Secondary outcomes

1

Description
knee function and recovery
Timepoint
1 month and 6 months post-surgery
Method of measurement
Knee injury and Osteoarthritis Outcome Score (KOOS)

2

Description
knee function and recovery
Timepoint
1 month and 6 months post-surgery
Method of measurement
Oxford Knee Score (OKS)

3

Description
Sleep Quality
Timepoint
1 month post-surgery
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

4

Description
Satisfaction with the surgical outcome
Timepoint
6 months post-surgery
Method of measurement
scale from 0 to 10

5

Description
Hospital length of stay
Timepoint
During hospitalization
Method of measurement
Calculating the number of days of hospitalization after surgery

Intervention groups

1

Description
Intervention group: Oral immediate-release oxycodone hydrochloride 5 mg every 12 hours for 4 weeks post-op.
Category
Treatment - Drugs

2

Description
Control group: Matching placebo tablets on same schedule.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital in Tehran
Full name of responsible person
Seyed Hadi Kalantar
Street address
Imam khomeini Hospital, Keshavarz blvrd, Tehran,Tehran,Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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?
No

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
Seyed Hadi Kalantar

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data will be shared after making patients in samples unidentifiable.
When the data will become available and for how long
With the publication of the article
To whom data/document is available
All Researchers
Under which criteria data/document could be used
Only statistical analysis is allowed
From where data/document is obtainable
as a supplementary
What processes are involved for a request to access data/document
All researchers will be given access
Comments