Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the Effect of Oral Oxycodone and Saphenous Nerve Block in Controlling the Acute Post-operative Pain in Patients Undergoing Knee Replacement Surgery

Protocol summary

Study aim

Comparison of the Effect of Oral Oxycodone and Saphenous Nerve Block in Controlling the Acute Post-operative Pain in Patients Undergoing Knee Replacement Surgery

Design

Prospective

Settings and conduct

In the first group, two hours before surgery and every six hours after the operation on the patient's request and the presence of pain, an oxycodone tablet is orally administered at a dose of 5 mg . In the other group an ultrasound guided saphenous nerve block with 16 cc of 0.5% bupivacaine, plus epinephrine with a concentration of 1/200000 is done. Study Place: Baqiyatolah Azam Hospital ,Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Aged 15-75 years 2- Candidates for knee replacement 3-Classification of American Society of Anesthesiology (ASA) I, II (Healthy or underlying controlled illness) Exclusion criteria: 1- Previous knee joint surgery 2- Bilateral surgery 3- Kidney or liver function disorders 4- History of allergic sensitization to Non-Steroidal Anti-Inflammatory Drugs 5- History of addiction 6- History of chronic drug use for pain control 7- History of cardiovascular or severe respiratory disease 8- History of neurological disease with lower limb involvement 9- History of gastrointestinal ulcer 10- Failure of block

Intervention groups

In one group, oral oxycodone was used and in the other group, the ultrasound guided saphenous nerve block was used to control post-operative pain

Main outcome variables

The amount of postoperative pain based on VAS (Visual Analog Scale) score and the complications of each methods, such as nausea, vomiting and hypotension at 2,6,12,24 hours after surgery are examined.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170826035905N3**
Registration date: **2018-11-21, 1397/08/30**
Registration timing: **retrospective**

Last update: **2018-11-21, 1397/08/30**
Update count: **0**

Registration date

2018-11-21, 1397/08/30

Registrant information

Name

Nader Ali Nazemian Yazdi

Name of organization / entity

Tehran University of Medical Sciences/Amir Alam Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8830 3621

Email address

nnazemian@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2016-05-30, 1395/03/10

Actual recruitment end date

2017-05-31, 1396/03/10

Trial completion date

2017-06-01, 1396/03/11

Scientific title

Comparison of the Effect of Oral Oxycodone and Saphenous Nerve Block in Controlling the Acute Post-operative Pain in Patients Undergoing Knee Replacement Surgery

Public title

Evaluation of the effect of oral Oxycodone and Saphenous nerve block in knee replacement surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 15 and 75 years Candidates for knee replacement surgery Classification for American Society of Anesthesiology (ASA) I, II (patients with normal or mild and controlled underlying disease).

Exclusion criteria:

Previous knee joint surgery Bilateral surgery Kidney or liver function disorders, History of allergic sensitization to non-steroidal anti-inflammatory drugs History of addiction History of chronic drug use for pain control History of severe cardiovascular or respiratory disease History of neurological disease with lower limb involvement History of gastrointestinal ulcer Failure of block

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers chart

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator is blind about the study groups and the investigator is unaware of the consequences of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Researches of the Baqiyatallah University of Medical Sciences

Street address

Mollasadra Ave., Baqiyatallah University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

435793666 1

Approval date

2016-03-14, 1394/12/24

Ethics committee reference number

ir.bmsu.rec.1394.248

Health conditions studied

1

Description of health condition studied

Regional Anesthesia and Pain Management

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Pain

Timepoint

2,6,12,24 hours after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Nausea

Timepoint

2,6,12,24 hours after surgery

Method of measurement

Rating variable :Mild(0-1) Moderate(2-3) Severe(more than 3)

2

Description
Sedation
Timepoint
2,6,12,24 hours after surgery
Method of measurement
Rating variable :Mild(0-1) Moderate(2-3) Severe(more than 3)

Intervention groups

1

Description
In the first group, oral oxycodone was administered at a dose of 5 mg two hours before surgery and every six hours after operation based on patient request and presence of pain
Category
Treatment - Drugs

2

Description
In the second group the saphenous nerve block is performed in the adductor canal under ultrasound guide with 16 cc bupivacaine 0.5% and epinephrine with concentration of 1: 200,000 .
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatolah Azam Hospital
Full name of responsible person
Nader Ali Nazemian Yazdi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences/Trauma Research Center
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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
Baqiyatallah University of Medical Sciences/Trauma Research Center
Proportion provided by this source
10
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
Nader Ali Nazemian Yazdi
Position
Assistant Professor of Anesthesiology
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
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