

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 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

2,6,12,24 hours after surgery are examined.

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

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

Street address

Mollasadra Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences/Trauma Research Center

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

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

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Nader Ali Nazemian Yazdi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pain Management

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Position

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Latest degree

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Other areas of specialty/work

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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