Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing pain intensity and range of motion after using combination of NSAID and Acetaminophen with opioid analgesic protocol after high tibial osteotomy

Protocol summary

Study aim

Comparing pain intensity and range of motion after using combination of NSAID and Acetaminophen with opioid analgesic protocol after high tibial osteotomy in patients referred to Valiasr Faraja hospital in Tehran city.

Design

The design of this study is a parallel clinical trial in phase 2-3. It has a control group where patients will be assigned to study groups by block randomization method. The sample size is 30 patients. Blinding will not be done in this study.

Settings and conduct

The aim of this study is the effect of different combinations of pain relievers on pain intensity and range of motion of patients undergoing proximal tibial osteotomy in Valiasr Faraja hospital. Both patients and evaluators of study outcomes will know the type of painkillers received.

Participants/Inclusion and exclusion criteria

The most important conditions for entering the study are patients undergoing proximal tibial osteotomy and being physically active. The most important non-inclusion criteria are having pain and range of motion beyond the limit before surgery, patients experiencing infection during the study, and receiving a pain pump after surgery.

Intervention groups

In this study, two groups of patients receiving different analgesic compounds will be compared. The patients in the intervention group will receive NSAID and acetaminophen, and the patients in the control group will receive oxycodone opioid.

Main outcome variables

Range of motion; Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231217060438N1**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **prospective**

Last update: **2024-01-06, 1402/10/16**
Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

Name

seyed nima taheri taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2368

Email address

nimat92@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-15, 1402/10/25

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing pain intensity and range of motion after using combination of NSAID and Acetaminophen with opioid analgesic protocol after high tibial osteotomy

Public title
Comparing pain intensity and range of motion after high tibial osteotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing proximal tibial osteotomy Physically active people Age range of 20 to 50 years

Exclusion criteria:
having pain and range of motion outside the study limit before the operation Drug addiction Having a history of drug sensitivity to ibuprofen, acetaminophen, and oxycodone Patients with BMI higher than 40 Patients with a history of taking corticosteroid drugs Patients with a history of osteoporosis A patient who gets an infection after surgery A patient who is hospitalized again within three months A patient who receives a pain pump after surgery Sedentary people (less than 2 hours of physical activity per day) or with high activity such as runners (more than 10 hours of physical activity per day) Having a disorder in the knee ligaments Having severe DJD

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method was used in this study. The size of the blocks is considered to be six and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A, B. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of directorate of health, rescue and treatment of police headquarter

Street address
Deputy Health, Relief and Treatment Naja, Edward Brown St., Northern Karger St., Enghelabl Square, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-11-25, 1402/09/04

Ethics committee reference number
IR.SBMU.TEB.POLICE.REC.1402.068

Health conditions studied

1

Description of health condition studied
Proximal Tibial Osteotomy

ICD-10 code
S83.1

ICD-10 code description
Subluxation and dislocation of knee

Primary outcomes

1

Description
intensity of pain

Timepoint
1, 2, 7, 30, 90 days after surgery

Method of measurement
Visual Analogue Scale (VAS)

2

Description
range of motion

Timepoint
1، 2، 7، 30، 90 days after surgery

Method of measurement
Orthopedic gonia

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients assigned to the first group will receive NSAID analgesic protocol (ibuprofen) and acetaminophen. In this group, they will take 3 tablets of ibuprofen (600 mg) every 8 hours, and two tablets of acetaminophen (500 mg) every 4 hours after taking the NSAID.
Category
Treatment - Drugs

2

Description
Intervention group 2:The intervention of the second group is oxycodone opioid, which will be used as a pain reliever after surgery. Oxycodone is 10.5 mg every 6 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Faraja Hospital
Full name of responsible person
Seyed Nima Taheri
Street address
Valiasr Faraja hospital, above Mirdamad, Valiasr Street, Tehran
City
Tehran
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+98 21 8877 0022
Email
nimat92@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Applied Research Center, Deputy Behdad Police Command
Full name of responsible person
Syrus Afshar
Street address
Valiasr Faraja hospital, above Vanak Square, Valiasr Street, Tehran
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Email
nimat92@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Applied Research Center, Deputy Behdad Police Command
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Applied Research Center, Deputy Behdad Police Command
Full name of responsible person
Seyed Nima Taheri
Position
Non-academic specialist doctor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Valiasr Faraja hospital, above Vanak Square, Valiasr Street, Tehran
City
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Applied Research Center, Deputy Behdad Police

Command

Full name of responsible person
Seyed Nima Taheri

Position
Non-academic specialist doctor

Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Applied Research Center, Deputy Behdad Police Command

Full name of responsible person
Seyed Nima Taheri

Position
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Latest degree
Specialist

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Phone
+98 21 8123 5481

Email
nimat92@yahoo.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
No - There is not 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
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
Finding of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.

When the data will become available and for how long
Availability six months after the end of study.

To whom data/document is available
Specialists in orthopedics, surgery, anesthesiologists, internists.

Under which criteria data/document could be used
Requests may be made by organizations, journals or project supervisors. These requests will be read by the research team under the supervision of a institute representative, and if the requests are reasonable, relevant de-identified data will be sent. This request may be some results of biomarkers or codes performed for data analysis.

From where data/document is obtainable
The initial request can be sent to the e-mail of the people who are in the scientific and general response section of the trial (nimat92@yahoo.com). Also, the applicants can go to the Applied Research Center of Behdad Vice-Chancellor located in Valiasr Faraja Hospital in Tehran or the Clinical Trial Center of Iran which It is referred to in the central library of Iran University of Medical Sciences.

What processes are involved for a request to access data/document
After the institution agrees to send data for requests, depending on whether the requester is inside the country or abroad, and also according to the type of requested data, the time to respond to the requests will be different. Finally, no request will take more than one month.

Comments