Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Effect of Remifentanil on Postoperative Pain in Knee Arthroscopic Surgery; a Randomized Controlled Clinical Trial

Protocol summary

Study aim
Reduction of pain and hospitalization of patients undergoing knee arthroscopy by intra-articular injection of remifentanil

Design
The present study is a double-blind that Phase of clinical trial is phase 2-3 with 60 patients undergoing meniscus knee arthroscopy.

Settings and conduct
In this double blind randomized clinical trial study, 60 patients were studied in Imam Reza hospital Mashhad, Iran between 2018 and 2020. Individuals were candidates for knee surgery with arthroscopic ASA grade one and two will be entered in this study. Then patients who had inclusion criteria will be randomly divided into two groups. The first group included patients receiving intra-articular remifentanil and the second group (control) included those receiving the same volume of normal intra-articular saline. The physician will then inject the patient without knowing the solution used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals who completed the Consciousness Questionnaire for Arthroscopic Knee Arthroscopy and were candidates for Knee Arthroscopy Surgery according to American Society of Anesthesiologists Classification Class One and Two . Exclusion criteria: Using opioids Using Nonsteroidal anti-inflammatory drugs in 24 hours before surgery Diabetic neuropathy Neuromuscular diseases People with a history of infection and malignancy Knee surgery history (patients requiring any procedure except knee arthroscopic meniscectomy) History of medicinal allergies history of renal failure liver dysfunction ischemic and valvular heart disease cases required repeated opioid intake during surgery, complicated knee surgery hypertension

Intervention groups
Intervention group: intra-articular injection of Remifentanil will be done. Control group: placebo intra-articular injection will be done.

Main outcome variables
Pain

General information

Reason for update
Primary version has some errors and was not complete

Acronym

IRCT registration information
IRCT registration number: **IRCT20191017045137N1**
Registration date: **2020-01-04, 1398/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-27, 1400/01/07**
Update count: **1**

Registration date
2020-01-04, 1398/10/14

Registrant information

Name
Azita Farahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-11, 1398/01/22

Expected recruitment end date
2020-04-11, 1399/01/23

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Remifentanil on Postoperative Pain in Knee Arthroscopic Surgery; a Randomized Controlled Clinical Trial

Public title
Effect of Remifentanil on Postoperative Pain in Knee Arthroscopic Surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for Knee Arthroscopic Surgery American Society of Anesthesiologists Classification Class One and Two
Exclusion criteria:
Using opioids Using Nonsteroidal anti-inflammatory drugs in 48 hours before surgery Diabetic neuropathy Neuromuscular diseases People with a history of infection and malignancy Knee surgery history (patients requiring any procedure except knee arthroscopic meniscectomy) History of medicinal allergies history of renal failure liver dysfunction ischemic and valvular heart disease cases that required repeated opioid intake during surgery patients with complicated knee surgery
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Computer generated randomization, using www.randomization.com
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and the person who injects the drug do not aware of the type of drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghaem Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.614

Health conditions studied

1

Description of health condition studied
Knee Meniscus Injury
ICD-10 code
S83.7
ICD-10 code description
Injury to multiple structures of knee

Primary outcomes

1

Description
Pain
Timepoint
After surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 200 µg of Remifentanil, 25 ml volume dissolved in normal saline at the end of surgery by an orthopedic colleague who is unaware of the drug.
Category
Prevention

2

Description

Control group: 25 cc of normal saline intra-articular will be injected at the end of surgery.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Dr Mohammad Alipour

Street address
Ghaem Hospital, Taghi Abad Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research, Mashhad University of Medical Science

Street address
Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street

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Ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohammad Alipour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
As a research paper

When the data will become available and for how long
2020

To whom data/document is available
researchers

Under which criteria data/document could be used
medical students

From where data/document is obtainable
sent an email

What processes are involved for a request to access data/document
sent an email

Comments