

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of intraarticular and periarticular injection of cocktail of morphin epinephrin ropivacain ketorolac on eliminating the postoperative pain after total knee arthroplasty in patients with knee degenerative joint disease

Protocol summary

Study aim

Comparison of the effect of intraarticular and periarticular injection of cocktail of morphin epinephrin ropivacain ketorolac on eliminating the postoperative pain after total knee arthroplasty in patients with knee degenerative joint disease

Design

triple blinded randomised control trial

Settings and conduct

Imam Khomeini hospital, orthopedic surgery room

Participants/Inclusion and exclusion criteria

those with knee osteoarthritis referred to Imam Khomeini hospital for total knee arthroplasty. inclusions: age 18-80 weight 50-120, ability to read wright persian language and complete informed consent form. exclusions: drug dependence, drug hypersensitivity, neurologic, psychiatric, cardiac renal or liver comorbidity and those with inflammatory arthritis

Intervention groups

1. intraarticular injection of the analgesic cocktail(5mg morphin sulfate, 400 mg ropivacain, 30mg ketorolac, 0.6 cc epinephrin 1/1000) 100cc after suturing the knee capsule at the end of total knee arthroplasty 2. periarticular injection of analgesic cocktail 100cc after inserting the knee prosthesis 3. periarticular injection of analgesic cocktail 50cc after prosthesis instrumentation and injection of another 50cc of the cocktail after suturing the capsule at the end of the surgery

Main outcome variables

the amount of Morphin sulfate injection after the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051559N1**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Farzad Vosoughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 0873

Email address

farzadvosooghi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-15, 1400/03/25

Expected recruitment end date

2022-06-15, 1401/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intraarticular and periarticular injection of cocktail of morphin epinephrin

ropivacain ketorolac on eliminating the postoperative pain after total knee arthroplasty in patients with knee degenerative joint disease

Public title

Comparison of the effect of intraarticular and periarticular injection of cocktail of morphin epinephrin ropivacain ketorolac on eliminating the postoperative pain after total knee arthroplasty in patients with knee degenerative joint disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

those aged 18-80 weight between 50-120 kg ability to read, write and complete informed consent

Exclusion criteria:

drug sensitivity drug dependence neurologic disease psychiatric illness cardiac disease liver disease cardiac arrythmia Diabetes neuromuscular problem inflammatory arthritis e.g. RA renal disease

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization triple blind (the patient the analyser and the researcher gathering data are not informed of the type of allocation) the allocation of each patient is determined according to the numbers generated by randomization software and is documented in sealed envelope. during the operation, the envelope is opened and the surgeon is informed of the type of allocation at the time of prosthesis insertion by his operative staff.

Blinding (investigator's opinion)

Triple blinded

Blinding description

the allocation of each patient is determined according to the numbers generated by randomization software and is documented in sealed envelope. during the operation, the envelope is opened and the surgeon is informed of the type of allocation at the time of prosthesis insertion by his operative staff.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical review board of imam khomeini hospital, tehran university of medical sciences

Street address

Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran1419733141, Iran.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.434

Health conditions studied

1

Description of health condition studied

knee degenerative joint disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

amount of post operative morphin sulfate injection after the total knee arthroplasty

Timepoint

during 72 hr after the total knee arthroplasty

Method of measurement

mg morphin injected by the nursery and documented in the patien's documents

Secondary outcomes

1

Description

visual analogue scale

Timepoint

during 72 h postoperatively 1 week and 1 months after surgery

Method of measurement

1 to 10 based on the VAS scale

2

Description

WOMAC

Timepoint

1 DAY before OR, 1 week and 1 month after OR

Method of measurement

womac scale

3

Description

KSS

Timepoint

1 DAY before OR, 1 week and 1 month after OR

Method of measurement

KSS scale

Intervention groups

1

Description

Intervention group: intrarticular analgesic cocktail (MS, ropivacain, ketorolac, epinephrin) injection 100 cc

Category

Rehabilitation

2

Description

Intervention group: periarticular injection of analgesic cocktail 100 cc

Category

Rehabilitation

3

Description

Intervention group: intra (50cc) and peri articular (50 cc) injection of analgesic cocktail

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

farzad vosoughi

Street address

Joint Reconstruction Research Center,
Orthopedicsurgery department, Imam Khomeini
Hospital, End of Keshavarz Blvd, Tehran1419733141,
Iran.

City

tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8827 0873

Email

farzadvosooghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

farzad vosoughi

Street address

Joint Reconstruction Research Center,
Orthopedicsurgery department, Imam Khomeini
Hospital, End of Keshavarz Blvd, Tehran1419733141,
Iran.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8827 0873

Email

farzadvosooghi@gmail.com

Grant name

Grant code / Reference number

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

Yes

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 mohammad javad mortazavi

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Joint Reconstruction Research Center,
Orthopedicsurgery department, Imam Khomeini
Hospital, End of Keshavarz Blvd, Tehran1419733141,
Iran.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8827 0873

Email

smjmort@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

farzad vosoughi

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Joint Reconstruction Research Center,
Orthopedicsurgery department, Imam Khomeini
Hospital, End of Keshavarz Blvd, Tehran1419733141,
Iran.

City

tehran

Province

Tehran

Postal code

1419733141

Phone

009888270873

Email

farzadvosooghi@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

farzad vosoughi

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Joint Reconstruction Research Center,
Orthopedicsurgery department, Imam Khomeini
Hospital, End of Keshavarz Blvd, Tehran1419733141,
Iran.

City

tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8827 0873

Email

farzadvosooghi@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Comparision of the effect of intraarticular and
periarticular injection of cocktail of morphin epinephrin
ropivacain ketorolac on eliminating the postoperative
pain after total knee arthroplasty in knee arthrotic
patients referred to the joint reconstruction research
center of imamkhomeini hospital

When the data will become available and for how long

at the end of the study

To whom data/document is available

academic institution

Under which criteria data/document could be used

scientific journal

From where data/document is obtainable

for comparing the clinical outcom the data is aimed to be
shared online

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

email request

Comments