

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

comparison of the Effectiveness of pre-operative intravenous ketamine administration with placebo in controlling post-operative pain in patients with advanced knee osteoarthritis undergoing total knee arthroplasty

Protocol summary

Study aim

the purpose of this study is to evaluate the safety and efficacy of ketamine to reduce post total knee arthroplasty pain

Design

this is a prospective triple blind single center comparative 2 arm RCT to compare the effectiveness of on bolus dose of intravenous ketamine on post-operative pain after total knee arthroplasty. 60 patients are equally and randomly assigned to group A (ketamine) or group B (PLACEBO/normal saline)

Settings and conduct

The study will be run in Shariati hospital. Tehran university of medical sciences. After spinal anesthesia single bolus dose of ketamine or placebo is intravenously injected the patients. anesthesiologist, surgeons, data collectors and statistician are blinded.

Participants/Inclusion and exclusion criteria

-Inclusion criteria are : patients between 18 and 85 years old with end stage knee osteoarthritis undergoing unilateral, primary TKA(total knee arthroplasty) - exclusion criteria are : opium sensitivity or ketamine contraindication Rheumatoid arthritis, patients unable to understand the visual analog scale previous history of knee arthroplasty, simultaneous bilateral arthroplasty patients receiving general anesthesia or a nerve block. body mass index greater than 40 kg/m², preoperative ketamine or chronic narcotic usage discharged before the first 24 hour

Intervention groups

group A(placebo): ketamine 0.5 mg per kg of patient body weight (total volume will be increased to 5 ml by adding normal saline) group B (drug): 5 ml of normal saline

Main outcome variables

post operative pain at 2,6,12,24 hour and 10 and 42 days post operation are evaluated. the time of first

analgesic request.total analgesic consumption.duration of hospitalization,rate of complications,knee range of motion,patient satisfaction and subgroup analysis according to age,sex,deformity and stage of soft tissue release will be evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054298N1**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Sina Javidmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2221 6594

Email address

sinajavidmehr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-01, 1401/03/11

Expected recruitment end date

2022-08-01, 1401/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the Effectiveness of pre-operative intravenous ketamine administration with placebo in controlling post-operative pain in patients with advanced knee osteoarthritis undergoing total knee arthroplasty

Public title

effect of ketamine on controlling pain after total knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Between 18 and 85 years old undergoing unilateral, primary total knee arthroplasty "TKA" for degenerative end-stage osteoarthritis(OA) of the knee (score of >2 on Kellgren-Lawrence scale).

Exclusion criteria:

patients who refuse to participate, classified as ASA IV or V by the American Society of Anesthesiologists, body mass index greater than 40 kg/m², rheumatoid arthritis, contraindication or allergy to opioid pain medications allergy to amide or sulpha anesthetics, unable to understand the visual analog scale (VAS) , any preoperative ketamine or chronic narcotic usage (>10mg systemic morphine equivalents daily) as it causes opioids tolerance , those who are discharged before the first 24 hours postoperatively, previous history of knee arthroplasty, prior surgery on the ipsilateral knee within 6 months, simultaneous bilateral arthroplasty, the patients receiving general anesthesia or a nerve block patients with an ejection fraction of less than 30%, creatinine clearance of less than 30mL/min, chronic liver disease, any neurologic or psychiatric disorder (including bipolar, post-traumatic stress disorder, schizophrenia), chronic alcohol abuse

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization will be used to produce randomized

sequences .each block will consists of 4 sites including 2 placebos(B) and 2 drugs(A).That way,6 randomization pattern(permutations of 2 from 4) will be available. Random choosing of the above mentioned sites will be performed based on www.randomization.org. and will be performed Hiddenly . The placebo/drug that each patient receives will be concealed from the physician, statistician and the patient. 30 concealed envelopes that contain instructions for mixing solutions for group A, and the other 30 for group B are put on each other. content of each envelope is based on previously instructed randomization pattern. After entering the patient to the operating room ,an anesthesiology technician not involving in other part of the study will choose the first envelope from the top and follow the instructions of preparing the syringe content. He then documents the patient's ID and predetermined group. thereafter, he does not partake in any subsequent part of the study .after data gathering and completion of the analysis,the A/B labels will be decoded to prepare the final manuscript. None of the other investigators involved in patient management or data collection is aware of the group assignment

Blinding (investigator's opinion)

Triple blinded

Blinding description

60 identical sequentially numbered, opaque, sealed, and stapled envelopes(30 envelopes contain instructions for mixing solutions for group A, and the other 30 for group B) are put on each other. content of each envelope is based on previously instructed block randomization pattern. After entering the patient to the operating room ,an anesthesiology technician not involving in other part of the study will choose the first envelope from the top and follow the instructions of preparing the syringe content. The volume of each syringes will reaches 5 cc by adding normal saline so all of the injected syringes in A/B groups contains the same volume. Also, both ketamine and normal saline study solutions had the same physical properties: clear liquids with no distinctive odor .Therefore, they can not be identified or differentiated by sight or smell . The technician then documents the patient's characteristics and A/B intervention groups. The patient ,the surgeon and data collecting team members are blind of the injected liquid. After data gathering and completion of the analysis the A/B labels will be decoded to prepare the final manuscript.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Orthopedics ward, Shariati Hospital, Jalale ale ahmad Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1408

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

2 hour , 6hour , 12 hour ,24 hour ,10 days ,42 days post operative

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

maximum post op knee flexion

Timepoint

at discharge ,post op day 10 , post op day 42

Method of measurement

orthopedic ruler

2

Description

hospital stay duration

Timepoint

from the end of operation to discharge time

Method of measurement

time-hour

3

Description

time of first morphine request

Timepoint

from the end of operation to first time of morphine request

Method of measurement

time-hour

4

Description

total morphine(analgesics) consumption

Timepoint

at the time of discharge

Method of measurement

mg/kg....patient document

Intervention groups

1

Description

Intervention group: 0.5 miligram per kilogram of body weight ketamine in 5 cc syringe and increase to total volume of 5ml with normal saline. after spinal anesthesia and before incision, intravenously injected in 2 minutes.

Category

Treatment - Drugs

2

Description

Control group: 5 cc normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Farzad Fatehi

Street address

Shariati Hospital, Jalale ale ahmad Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2652

Fax

+98 21 8863 3039

Email

Shariatiresearch@sina.tums.ac.ir

Web page address

<https://shariati.tums.ac.ir/Home>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

TUMS central building, Ghods street, Keshavarz Blvd,
Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3686

Fax

+98 21 4291 1450

Email

vcr@tums.ac.ir

Web page address

<https://tums.ac.ir/>

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

Sina Javidmehr

Position

knee fellowship assistant

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

+98 21 8866 3039

Email

sinajavidmehr@gmail.com

Web page address

<https://shariati.tums.ac.ir/Show/Item/2>

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sina Javidmehr

Position

knee fellowship assistant

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

sinajavidmehr@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sina Javidmehr

Position

knee fellowship assistant

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Shariati Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

sinajavidmehr@gmail.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

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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available