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 an 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

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Sina Javidmehr

Name of organization / entity

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Iran (Islamic Republic of)

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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 date 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
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Sponsors / Funding sources

1

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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
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
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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

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