Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

The Comparison between intraarticular knee injection (Morphine, ketorolac) with and without Tranxamic acid following arthroscopic ACL reconstruction surgery in reducing pain and assessing functional outcomes in patient with isolated ACL injury

Protocol summary

Study aim
Comparing the effectiveness of intra-articular injection of morphine, ketorolac with and without injection Tranexamic acid in reducing pain and short-term clinical outcome after arthroscopic reconstruction of anterior cruciate ligament in patients with exclusive injury of ACL

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 100 patients. For randomization, the random numbers given to each of them by the computer enter the control group or the intervention group.

Settings and conduct
Patients in Imam Khomeini Hospital, Tehran, after meeting the entry criteria and obtaining informed consent, will be divided into 2 control and intervention groups, according to the sample size.

Participants/Inclusion and exclusion criteria
Individuals with exclusive rupture of the ACL in the age range of 15 to 60 years and weighing <100 kg who are able to read and write to give written informed consent and cooperate in the study were included. And people with drug sensitivity or a history of drug dependence who have neurological and psychiatric problems, heart, kidney, liver disease and cardiac arrhythmia, diabetes, neuromuscular disease, inflammatory joint arthritis such as rheumatoid arthritis, or performing osteotomy surgery or the presence of accompanying cartilage damage or meniscal tear, They are being excluded from the study

Intervention groups
Intervention group: 30mg Ketorolac ampoule(1cc) 5mg morphine sulfate(0.5cc) 1gr Tranexamic acid (10cc) 100 mg of lidocaine (5 cc) 23.5cc of normal saline solution
Control group: 30mg Ketorolac ampoule(1cc) 5mg morphine sulfate(0.5cc) 100 mg of lidocaine (5 cc) 33.5cc of normal saline solution

Main outcome variables
Reducing the amount of pain and increasing the satisfaction and rehabilitation of patients after arthroscopic reconstruction of the ACL

General information

Reason for update
updating some of protocol fields

Acronym

IRCT registration information
IRCT registration number: **IRCT20221230056983N1**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-30, 1403/11/11**
Update count: **1**

Registration date
2023-02-25, 1401/12/06

Registrant information

Name
Behzad Nezhadtabrizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6658 1653

Email address
tabrizibehzad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-01, 1401/01/12

Expected recruitment end date
2023-10-31, 1402/08/09
Actual recruitment start date
2022-04-01, 1401/01/12
Actual recruitment end date
2023-10-31, 1402/08/09
Trial completion date
2024-01-29, 1402/11/09

Scientific title
The Comparison between intraarticular knee injection (Morphine, ketorolac) with and without Tranxamic acid following arthroscopic ACL reconstruction surgery in reducing pain and assessing functional outcomes in patient with isolated ACL injury

Public title
Investigating the effectiveness of intra-articular injection painkillers after cruciate ligament surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
an isolated, unilateral, chronic ACL tear Ability to read and write to give informed written consent and cooperate in the study Use of hamstring autograft American Society of Anesthesiologists (ASA) physical status of I
Exclusion criteria:
Drug sensitivity multi-ligament injuries bilateral ACL tears acute ACL tears bony deformities a history of hematologic conditions or ischemic attacks patients receiving anticoagulant therapy
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Table of random numbers (four block) by site randomization.com
Blinding (investigator's opinion)
Triple blinded
Blinding description
In our study, both the patients and the researchers are blinded to the prescription of the intervention drug, and the surgeon simply divides the patients into 2 groups, with and without the prescription of the drug, based on the argument of random numbers
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
Joint Reconstruction Research Center, Orthopedic Department, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2022-08-30, 1401/06/08
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.134

Health conditions studied

1

Description of health condition studied
isolated anterior cruciate ligament injury
ICD-10 code
S83.5
ICD-10 code description
Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

Primary outcomes

1

Description
pain variables including the amount of pain based on Visual Analogue Scale (VAS)
Timepoint
The pain level of the patients is based on the Visual Analoque Scale or VAS with a score from 1 to 10, which is measured in the intervals of one hour, two hours, 3 hours, 6 hours, 12 hours, one week, one month and three months after the operation.
Method of measurement
The level of patient satisfaction are measured based on the Visual Analogue Scale index

2

Description
Functional variables in patients including Knee Injury and Osteoarthritis Outcome Score (KOOS).
Timepoint
It is measured before surgery, one month and three months after surgery.
Method of measurement
The score of the KOOS or Knee injury and Osteoarthritis Outcome Score questionnaire examines the patient in 5 areas and its score is 0 to 100%.

Secondary outcomes

1

Description
Functional variables in patients including Lysholm
Timepoint
Lysholm questionnaire score from 0 to 100, before surgery, one hour, one month and three months after surgery.
Method of measurement
The performance of all patients is completed and evaluated based on the Lysholm questionnaire

Intervention groups

1

Description
Control group: Intra-articular injection of 40 cc of analgesic cocktail after surgery including: 30 mg Ketorolac ampoule (1 cc), 5 mg of morphine sulfate (0.5 cc),100 mg of lidocaine (5 cc), 33.5 cc of normal solution Saline; All made by Iranian pharmaceutical companies
Category
Treatment - Drugs

2

Description
Intervention group: Intra-articular injection of 40 cc of analgesic cocktail after surgery including: 30 mg Ketorolac ampoule (1 cc), 5 mg of morphine sulfate (0.5 cc), 1 gram of tranexamic acid (TXA) (10 cc)100 mg of lidocaine (5 cc) 23.5 cc normal saline solution; All made by Iranian pharmaceutical companies
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
Full name of responsible person
Mohammad Ayati Firozabadi
Street address
Joint Reconstruction Research Center, Orthopedic Department, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1653
Email
dr.mohammad.ayati@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fatuhi
Street address
6th floor of Research and Technology Vice-Chancellor, Central Organization of the Tehran University, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
Web page address
https://vcr.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
Behzad Nezhad Tabrizi
Position
orthopedic resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Joint Reconstruction Research Center, Orthopedic Department, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
009892166581653
Email
tabrizibehzad@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ayati Firozabadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Joint Reconstruction Research Center, Orthopedic Department, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1653
Email
dr.mohammad.ayati@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Behzad Nezhad Tabrizi
Position
orthopedic resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Joint Reconstruction Research Center, Orthopedic Department, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1653
Email
tabrizibehzad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
ask for IPD through corresponding investigator
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
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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