

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Intra-Articular Injection of Ketorolac versus Placebo for Post-Arthroscopic Pain Control in Patients with Knee Ligaments and Menisci injuries

Protocol summary

Summary

Post operative pain as affected physiological activity may adverse effects on surgery results and control of acute post operative pain can result improvement in patients clinical activity. Non-steroidal anti-inflammatory drugs result in better post operative rehabilitation and early ambulation and improvement in range of motion, by reducing inflammatory responses occurred after operation. In this study, 60 patients with knee ligaments or menisci injuries who admitted since March, 2015 and selected by inclusion and exclusion criteria and randomized. Then, they divided in two groups that each one contains 30 patients. They all treated by arthroscopic surgery. In case group Ketorolac injected in the knee joint immediately after surgery and in control group same volume of normal saline injected. If patients have severe pain in post-operative period, Intravenous opioid drugs would administered, as they wanted. Sleep disturbance in the first night after surgery and pain severity at 4 hours. 8 hours.12 hours and 24 hours after surgery registered and will be compared between two groups. The study is blinded for cases and researchers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040721640N1**
Registration date: **2015-04-27, 1394/02/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-27, 1394/02/07

Registrant information

Name

Abolfazl Mokhtari

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Intra-Articular Injection of Ketorolac versus Placebo for Post-Arthroscopic Pain Control in Patients with Knee Ligaments and Menisci injuries

Public title

Intra-Articular Injection of Ketorolac for Post-Arthroscopic Pain Control

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient agreement; No history of

cardiac and renal diseases; No history of lower limb fractures; No congenital disorders of extremities; No addiction to opioid. Exclusion criteria: History of regular analgesic and anti-inflammatory drugs; Neuropathies such as diabetes mellitus; Pregnancy; Patient with Coagulopathy; History of Gastro-Intestinal bleeding; History of Ketorolac-related complication or sensitivity

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah avenue

City

Tabriz

Postal code**Approval date**

2015-03-02, 1393/12/11

Ethics committee reference number

93187

Health conditions studied**1****Description of health condition studied**

Post-operative pain

ICD-10 code

S83.2, S83

ICD-10 code description

Tear of meniscus, Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

Primary outcomes**1****Description**

Knee Pain

Timepoint

24-hours after surgery

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

Sleep disorder

Timepoint

Night after surgery

Method of measurement

Subjective

2**Description**

Opioid requirement

Timepoint

24-hours after surgery

Method of measurement

Doses used

Intervention groups**1****Description**

Control group: Intra-Articular Injection of Saline

Category

Placebo

2**Description**

Intervention group: Intra-Articular Injection of Ketorolac

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Abolfazl Mokhtari

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Emam Reza hospital, Daneshgah avenue

City
Tabriz

2

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Abolfazl Mokhtari

Street address

Shohada hospital, Golestan avenue

City

Tabriz

3

Recruitment center

Name of recruitment center

Shahid Ghazi hospital

Full name of responsible person

Abolfazl Mokhtari

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Shahid Ghazi hospital, Daneshgah avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

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Tabriz University of Medical Sciences, Daneshgah avenue

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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

Vice Chancellor for research of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Doctor in Medicine, Orthopedics resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty