

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison the effects of intra-articular sole ropivacaine and combined ketorolac and ropivacain for pain control after knee arthroscopy surgeries in patients referred to Rasul and Firuzgar Hospitals between 2012-2013 years

#### Protocol summary

##### Summary

This study will be performed in order to investigate the effect of multi-model therapy for pain control after surgery. This clinical, randomized and double-blind trial will be conducted on 40 patients who get knee arthroscopy surgery in Rasul and Firuzgar Hospital during the year 2013 and are pleased for participating in this study; these patients do not have any diseases and recently did not use analgesic drugs. According to entrance and exit criteria the patients will be selected and their blood pressure and heart rate will be determined after connecting NIBP monitoring and pulse-oxy meter at operation room. These patients will be divided into two groups by Block Randomization method: 1- sole ropivacaine group, 2- combined ketorolac and ropivacain group. The first consequence including measurement of pain severity after entrance to recovery room and 2, 4, 8, 12, 18, 24 hours after surgery will be evaluated. The second consequence including nausea, vomiting and sedation will be assessed by expert nurses in recovery room and surgery part.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013073014218N1**  
Registration date: **2013-09-20, 1392/06/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-20, 1392/06/29

#### Registrant information

##### Name

Mehdi Masoomshahi

##### Name of organization / entity

Tehran University of medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4416 6270

##### Email address

m-masoomshahi@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2013-08-23, 1392/06/01

#### Expected recruitment end date

2014-08-23, 1393/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effects of intra-articular sole ropivacaine and combined ketorolac and ropivacain for pain control after knee arthroscopy surgeries in patients referred to Rasul and Firuzgar Hospitals between 2012-2013 years

#### Public title

the effectiveness of simultaneous use of analgesic drugs for pain control

#### Purpose

Prevention

## Inclusion/Exclusion criteria

Intrance criteria: to be pleased with participating in this study, the ages between 15 to 60 years old, to have knee arthroscopy surgery under general anesthesia Exit criteria: the history of using analgesics 24 hours before surgery, the history of bleeding or coagulation problems during the last month before surgery, renal and liver failure, severe cardiopulmonary, coagulopathy, morbid obesity (BMI<30 kg/m<sup>2</sup>), the history of nausea and vomiting after surgery, the history of migraine, the history of problems incidence during and after surgery, incidence of problems 24 hours after surgery which need the interference, known allergy, sensivity and contraindication about the use of opioid and non-opioid analgesics, pregnancy and lactation, the history of drug and alcohol abuse, being not to satisfied for participating in this study

### Age

From **15 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

it does not have

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

6th floor, Central Organization of Tehran University of Medical Sciences, corner of Ghods St., Keshavarz Ave.

##### City

Tehran

##### Postal code

##### Approval date

2013-08-21, 1392/05/30

##### Ethics committee reference number

92/D/1086/130

## Health conditions studied

### 1

#### Description of health condition studied

pain control after arthroscopy surgery

#### ICD-10 code

Z09.0 - Y4

#### ICD-10 code description

Z09.0:Follow-up examination after surgery for other conditions.Y45.9: Analgesic, antipyretic and anti-inflammatory drug, unspecified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

after entrance to recovery room and 2, 4, 8, 12, 18, 24 hours after surgery

#### Method of measurement

according to VAS (Visual Analog Scale), 0:no pain, 1-3:slight, 4-7:moderate, 8-10:sever

## Secondary outcomes

### 1

#### Description

nausea, vomiting and sedation

#### Timepoint

after entrance to recovery room and 2, 4, 8, 12, 18, 24 hours after surgery

#### Method of measurement

according to nausea and vomiting scale by patient's explaining about his/her symptoms (no nausea and vomiting/nausea/one to two order of nausea and vomiting/ nausea and vomiting more than two orders) - according to Ramsay sedation scale (1:Anxious or restless or both, 2:Cooperative, orientated and tranquil, 3:Responding to commands, 4:Brisk response to stimulus, 5:Sluggish response to stimulus, 6:No response to stimulus)

## Intervention groups

### 1

#### Description

In Control group 150 mg of ropivacain soluted in saline 0.9% will be infused inta-articularly by arthroscope at the end of arthroscopy surgery

#### Category

Treatment - Drugs

### 2

#### Description

In treatment group combination of 30 mg ketorolacand

150 mg ropivacain soluted in salin 0.9% will be infused inta-articularly by arthroscope at the end of arthroscopy surgery

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Rasul Akram Hospital

**Full name of responsible person**

Mehdi Masoomshahi (resident of anesthesiology)

**Street address**

**City**

Tehran

2

**Recruitment center**

**Name of recruitment center**

Firuzgar Hospital

**Full name of responsible person**

Mehdi Masoomshahi (resident of anesthesiology)

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Faranak Rokhtabnak

**Street address**

Firuzgar Hospital, Anesthesiology Group

**City**

Tehran

**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**

*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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mehdi Masoomshahi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

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**Web page address****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*