

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Efficacy of premedication with dextromethorphan and gabapentin alone or in combination for postoperative pain management in ACL and PCL knee arthroscopy with general anesthesia

Protocol summary

Study aim

efficacy of premedication with dextromethorphan and gabapentin alone or in combination for postoperative pain management in ACL and PCL knee arthroscopy with general anesthesia

Design

clinical trial with control group with parallel groups, blind, randomized

Settings and conduct

after designating operational teams and selecting patients with conditions , medications are dissolved and the drug is randomized to patients one hour before surgery and after anesthesia and at the end of the operation, the patient's pain and pain relief were collected (with NRS and Ramsy)

Participants/Inclusion and exclusion criteria

all patient for knee arthroscopy surgery under general anesthesia 18 to 60 years old ; ASA 1-2 class

Intervention groups

Intervention group: all patients undergoing arthroscopic knee arthroscopy with general anesthesia aged 18 to 60 years with ASA1-2 anesthetics class ; One hour before anesthesia, received a medication randomly Control group: negative

Main outcome variables

age ; gender ; pain ; drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020112N9**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **retrospective**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Pooya Derakhshan

Name of organization / entity

Birjand Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3234 1410

Email address

pooya_derakhshan@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2018-09-01, 1397/06/10

Actual recruitment start date

2017-09-01, 1396/06/10

Actual recruitment end date

2018-10-02, 1397/07/10

Trial completion date

2018-12-01, 1397/09/10

Scientific title

Efficacy of premedication with dextromethorphan and gabapentin alone or in combination for postoperative pain management in ACL and PCL knee arthroscopy with general anesthesia

Public title

Efficacy of premedication with dextromethorphan and gabapentin alone or in combination for postoperative

pain management in ligament of knee surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patient for knee arthroscopy surgery under general anesthesia 18 to 60 years old ASA 1-2 class

Exclusion criteria:

history of sensitivity to drugs that used in study Opium addiction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **114**

Actual sample size reached: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

use the random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

With the cooperation of the pharmaceutical company the drug Gabapentin and Dextromethorphan and the combination of these two were dissolved in the same volume and shape and color and based on the numbers the patients were given an oral dose one hour before surgery. The patients and the donor did not know which group were.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasoul Akram Hospital ; Mansouri St ; Satarkhan St

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-12-09, 1395/09/19

Ethics committee reference number

IR.IUMS.REC 1395.8921215111

Health conditions studied

1

Description of health condition studied

Efficacy of premedication with dextromethorphan and gabapentin alone or in combination for postoperative pain management in ACL and PCL knee arthroscopy with general anesthesia

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes

1

Description

pain rate

Timepoint

NRS scale at 0, 2, 4, 8, 12, and 24 hours

Method of measurement

Numeric Rating Scale ; Ramsay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : 100 mg oral Gabapentine, 1hour before surgery

Category

Treatment - Other

2

Description

Intervention group 2: 1mg/kg oral Dextromethorphan 1hour before surgery

Category

Treatment - Other

3

Description

Intervention group 3: 100 mg oral Gabapentine and 1mg/kg oral Dextromethorphan compound soluble in water, 1hour before surgery

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Pooya Derakhshan

Street address

Rasoul Akram Hospital ; Mansouri St ; Satarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

PR@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakooti

Street address

Iran University of Medical Sciences., next to Milad Tower., Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8163 3685

Email

PR@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

1

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

Iran University of Medical Sciences

Full name of responsible person

Pooya Derakhshan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Iran University of Medical Sciences., next to Milad Tower., Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8163 3685

Email

Pooya_derakhshan@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is 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

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

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

we have not yet set a conclusion

When the data will become available and for how long

we have not yet set a conclusion

To whom data/document is available

we have not yet set a conclusion

Under which criteria data/document could be used

we have not yet set a conclusion

From where data/document is obtainable

we have not yet set a conclusion

What processes are involved for a request to access data/document

we have not yet set a conclusion

Comments