

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison of peri-operative administration of pregabalin and duloxetine on post-op pain after TKA

Protocol summary

Study aim

The comparison of peri-operative administration of pregabalin and duloxetine effect on post-op pain after Total Knee Arthroplasty (TKA), for studying post-op pain score.

Design

Randomized controlled trial with 3 parallel group include 30 people (overall 90 people) and blinded outcome assessment, included patients choose one card from A-P-D cards and then divided in 3 groups randomly.

Settings and conduct

The people who give drugs to patients and evaluate the effect of drugs, don't know drug's name.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age:40-75, ASA I-II, TKA surgery, Spinal anesthesia Exclusion criteria: Lower limbs neuropathy, Therapy with Pregabalin and/or Duloxetine, Drug Abuse, Psychiatric patients that use drugs, Any comorbidity that prevents cooperation *, Allergy history to drugs which used in research like Pregabalin or Duloxetine, Patient dissatisfaction. * Pregabalin usage contraindications : 1. Heart conductive Block 2. Heart failure 3. Renal failure Duloxetine usage contraindication : 1. SIADH 2. Alcohol user 3. Drugs like MAOI that interacts with Duloxetine and causes serotonin syndrome 4. Closed angle glaucoma 5. History of orthostatic hypotension 6. Liver diseases 7. History of seizure 8. Renal failure Apotel usage contraindications: 1. Liver diseases 2. Alcohol user

Intervention groups

Group (D): Patients who use 30 mg Duloxetine, 1.5 hour before surgery Group(P) : Patients who use 75 mg Pregabalin, 1.5 hour before surgery and Group(A): Patients who use Placebo, 1.5 hour before surgery.

Main outcome variables

Determination of measure of pain with VAS;
Determination of consumption of painkiller among patients; Determination of prevalence of post-op complications; Determination of WOMAC questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044276N1**

Registration date: **2020-02-20, 1398/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-20, 1398/12/01**

Update count: **0**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name

Niloofer Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4437 2613

Email address

niloo.kh2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of peri-operative administration of pregabalin and duloxetine on post-op pain after TKA		sciences
Public title	The comparison of effect of pregabalin and duloxetine on post-op pain	Street address Iran university of medical sciences, Shahid Hemat highway,Tehran
Purpose	Treatment	City Tehran
Inclusion/Exclusion criteria		Province Tehran
Inclusion criteria:	Patients have TKA (total knee arthroplasty) surgery Patients have spinal anesthesia Patients are ASA I-II	Postal code 1449614535
Exclusion criteria:	Patients don't have consent Patients with allergy history of pregabalin and duloxetine Lower limbs neuropathy Drug abuse Therapy with pregabalin or deluxetine Any diseases that hinder patients to cooperate in this research	Approval date 2019-12-03, 1398/09/12
Age	From 40 years old to 75 years old	Ethics committee reference number IR.IUMS.FMD.REC.1398.378
Gender	Both	
Phase	3	
Groups that have been masked	- Participant - Care provider - Outcome assessor - Data analyser	
Sample size	Target sample size: 90	
Randomization (investigator's opinion)	Randomized	
Randomization description	In this research, with convenience method, we collect the numbers of calculated sample of intended patients. Then based on their numbers, we write A, B, C and patients choose from them.	
Blinding (investigator's opinion)	Double blinded	
Blinding description	In this research, the person who gives medications to patients and evaluates the effects of medications, doesn't know the type of medication.	
Placebo	Used	
Assignment	Parallel	
Other design features		
Secondary Ids	empty	
Ethics committees		
<u>1</u>		
Ethics committee		
Name of ethics committee	Ethics committee of Iran university of medical	

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Description

Control group: the patients who receive a placebo 1.5 hours before surgery and 12 and 24 hours after TKA.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul-e Akram hospital

Full name of responsible person

Niloofer Khosravi

Street address

Rasul-e Akram hospital, Mansouri Ave., Niyayesh St., Sattar-khan St., Tehran

City

Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Pain.Research.Center@gmail.com

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

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

Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pain

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Pain research center, Rasul-e Akram hospital, Mansouri Ave., Niyayesh St., Sattar-khan St., Tehran

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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

Yes - There is 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

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

Title and more details about the data/document

All data can be shared.

When the data will become available and for how long

The start of achieving is 6 months after the publishing of results

To whom data/document is available

Researchers and all people who work in universities and industries

Under which criteria data/document could be used

Usage of data for doing larger research is permissible.

From where data/document is obtainable

E-mail address: farimani@iums.ac.ir

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

E-mail the request from creditable university or company

Comments