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
Niloofar Khosravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4437 2613

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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

Public title
The comparison of effect of pregabalin and duloxetine on post-op pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients have TKA (total knee arthroplasty) surgery Patients have spinal anesthesia Patients are ASA I-II
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
Age
From **40 years** old to **75 years** old
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

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical sciences
Street address
Iran university of medical sciences, Shahid Hemat highway,Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-12-03, 1398/09/12
Ethics committee reference number
IR.IUMS.FMD.REC.1398.378

Health conditions studied

1

Description of health condition studied
Post-op pain; Total Knee Arthroplasty surgery
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
The pain score after total knee arthroplasty surgery
Timepoint
1,12,24,48 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: the patients who receive a 75 milligram pregabalin tablet 1.5 hours before surgery and 12 and 24 hours after TKA.
Category
Treatment - Drugs

2

Description
Second intervention group: the patients who receive a 30 milligram duloxetine tablet 1.5 hours before surgery and 12 and 24 hours after TKA.
Category
Treatment - Drugs

3

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
Niloofar Khosravi
Street address
Rasul-e Akram hospital, Mansouri Ave., Niyayesh St., Sattar-khan St.,Tehran
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Sponsors / Funding sources

1

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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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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