

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the efficacy of duloxetine and gabapentin in pain reduction in patients with knee osteoarthritis

Protocol summary

Study aim

In this study, we aim to compare the efficacy of Gabapentine compared to duloxetine in pain reduction and improvement of quality of life in patients with knee osteoarthritis.

Design

In this research, 150 patients with moderate to severe knee osteoarthritis with inclusion criteria and not having exclusion criteria referring to rheumatology clinics will be included. Patients will be randomly allocated to gabapentine, duloxetine and acetaminophen groups and each patient will be given a specific code.

Settings and conduct

After patients selection, they will be randomly allocated to mgabapentine, duloxetine and acetaminophen groups. Patients in both groups will be treated for 3 months and will be evaluated before intervention and 1 and 3 months later for pain severity according to visual analogue scale (VAS), functional status according to WOMAC questionnaire and quality of life according to SF-12 questionnaire. Patients and the person evaluating the treatment outcome will be unaware of the allocated groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Knee osteoarthritis with effusion; age between 45-75 years; ability to walk; having pain score of >5 according to VAS and >48 according to WOMAC questionnaire; Exclusion criteria: Other knee disorders; concomitant hip and ankle osteoarthritis; bursitis and perarticular disease; radicular pains; physiotherapy or intraarticular injection during the past 6 months; psychological disease; history of knee surgery; inflammatory joint disease; rheumatoid arthritis; fibromyalgia; active or recurrent pseudogout; malignancy; systemic diseases including renal of hepatic failure, uncontrolled blood pressure, diabetes mellitus; asthma in need of corticosteroids; corticosteroid use in less than 5 weeks prior to study

Intervention groups

In duloxetine group, treatment will begin with 30 mg daily and will increase to 60 mg daily. In Gabapentine group, treatment will begin with 300 mg daily and will increase to 600 mg daily. The third group will receive acetaminophen 1000 mg daily which could be increased to 2000 mg daily.

Main outcome variables

The main outcomes of the study are evaluating patients functional status using WOMAC (Western Ontario and McMaster Universities Osteoarthritis), pain severity using visual analogue scale and quality of life using SF-12 quality of life questionnaire which will be evaluated before intervention and 1 and 3 months after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035126N2**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **prospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Afshin Habibzadeh

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3352 2391

Email address

a.habibzade@arums.ac.ir

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2018-03-06, 1396/12/15

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of duloxetine and gabapentin in pain reduction in patients with knee osteoarthritis

Public title

Evaluating the efficacy of duloxetine and gabapentin in pain reduction in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

idiopathic knee osteoarthritis Age between 45-75 years ability to walk having pain score of >5 according to VAS and >48 according to WOMAC questionnaire

Exclusion criteria:

Other knee disorders Concomitant hip and ankle osteoarthritis Bursitis and perarticular disease radicular pains physiotherapy or intraarticular injection during the past 6 months psychological disease history of knee surgery inflammatory joint disease rheumatoid arthritis fibromyalgia active or recurrent pseudogout malignancy; systemic diseases including renal of hepatic failure, uncontrolled blood pressure, diabetes mellitus asthma in need of corticosteroids corticosteroid use in less than 5 weeks prior to study

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into three groups using random number blocks and using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person evaluating the treatment outcome will be blinded to the allocated groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah St.,

City

Ardabil

Province

Ardabil

Postal code

56189-85991

Approval date

2017-12-31, 1396/10/10

Ethics committee reference number

IR.ARUMS.REC.1396.190.

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

Knee osthoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

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

Pain

Timepoint

Before intervention and one and three months after intervention

Method of measurement

Using visual analogue scale (VAS)

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

Functional status

Timepoint

Before intervention and one and three months after intervention

Method of measurement

using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

2**Description**

quality of life

Timepoint

Before intervention and one and three months after intervention

Method of measurement

Using SF-12 quality of life questionnaire

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

Intervention group: In Duloxetine group, patients will be treated with 30 mg daily which will be increased to 60 mg daily.

Category

Treatment - Drugs

2**Description**

Intervention group: In gabapentine group, treatment will began with 300 mg daily and will be increased to 600 mg daily.

Category

Treatment - Drugs

3**Description**

Control group: Patients will be treated with 1000 mg acetaminophen which will be increased to 2000 mg daily.

Category

Treatment - Drugs

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

Ardabil Imam Khomeini Hospital

Full name of responsible person

Hamed Mohebi

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Imam Khomeini Hospital, Ataei Ave.,

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

Yes

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Afshin Habibzadeh

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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