Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Effetiveness of Duloxetine on severity of pain and quality of life in chronic low back pain in patients who had posterior spinal fixation (PSF)

Protocol summary

Study aim
The effectiveness of duloxetine on quality of life and severity of pain is assessed in patients with chronic low back pain who have undergone posterior spinal fixation surgery.

Design
Randomized, double blind , placebo-controlled Simple or unlimited randomization with coin throwing in such a way that coins are thrown according to the number of members and individuals are randomly assigned.

Settings and conduct
This trial will be conducted in neurosurgery department of Rasoul-e Akram hospital in Tehran . 50 patients with chronic low back pain who are candidates for posterior spinal fixation surgery are divided into two groups (drugs and placebo). They fill out VAS and SF-36 questionnaires before surgery and after 6 weeks of taking 30 mg of doloxacin or placebo.

Participants/Inclusion and exclusion criteria
Patients older than 18 years old and younger than 80 , must discontinue any medication that could interfere with their pain such as nonopioid or opioid drugs , antidepressants and anticonvulsants at least for 6 months before surgery , non pharmacological pain-relieving procedures such as acupuncture or physical therapies Exclusion criterias are : prior use of opioids , depression , use of antidepressants , drug abuse , pregnancy and breast feeding , severe coexisting diseases such as heart failure , severe hypertension , convulsion and kidney dysfunction.

Intervention groups
The patients with chronic low back pain (more than 3 months) and candidate for posterior spinal fixation are randomised divide in two groups (duloxetine or placebo). In first step all patients will fill the VAS and SF-36 and questionnaires and after the surgery the drug group will receive 30 mg of duloxetine and placebo group will receive placebo for 6 weeks. After this time all the patients again will fill the questionnaires.

Main outcome variables
Changes in quality of life standards Changes in pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191210045685N1**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **retrospective**

Last update: **2020-07-04, 1399/04/14**
Update count: **0**

Registration date
2020-07-04, 1399/04/14

Registrant information

Name
Arezoo Samadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2227 6936

Email address
arezoosamadi1980@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-08-06, 1398/05/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effetiveness of Duloxetine on severity of pain and quality of life in chronic low back pain in patients who had posterior spinal fixation (PSF)

Public title

Effectiveness of duloxetine in chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients older than 18 years old and younger than 80 with chronic low back pain (more than 3 months duration) who are candidate for posterior spinal fixation surgery. All patients have to discontinue any medication that could interfere with their pain such as nonopioid or opioid drugs , antidepressants and anticonvulsants at least for 6 months before surgery. Non pharmacological pain-relieving procedures such as acupuncture or physical therapies are not allowed during the study.

Exclusion criteria:

prior use of opioids , antidepressants , drug abuse depression pregnancy and breast feeding severe coexisting diseases such as heart failure , severe hypertension , convulsion and kidney dysfunction

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple or unlimited randomization with coin throwing in such a way that coins are thrown according to the number of the members and individuals are randomly assigned to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are explained that they will be randomly assigned to one of the two groups of drugs or placebo, but they do not know which group they are in. The resident in charge of filling out the questionnaires and distributing the medicine or placebo is also not aware of them and distributes the medicine and placebo in the same containers among the patients. The same is true of the analyzer.

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

No. 3/5/1, 16th velenjak St., Tehran , Iran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۳۸۴۵۱

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR. IUMS.FMD.REC.1398.016

Health conditions studied

1

Description of health condition studied

Effectiveness of duloxetine in posterior spinal fixation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Effectiveness of duloxetine on quality of life in chronic low back pain in patients who had posterior spinal fixation measured with SF36 questionnaire / Effectiveness of duloxetine on severity of pain in chronic low back pain in patients who had posterior spinal fixation measured with VAS questionnaire.

Timepoint

all patients will fill the questionnaires at first step of study and one more 6 weeks later

Method of measurement

SF36 questionnaire / VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After posterior spinal fixation surgery case group receive 30 mg of duloxetine for 6 weeks.
Category
Treatment - Drugs

2

Description
Control group: : After posterior spinal fixation surgery control group receive placebo for 6 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul -e Akram Hospital Iran University of Medical Sciences
Full name of responsible person
Arezoo Samadi
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No. 3/5/1/2 ,16th Ave. Velenjak St. 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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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
Arezoo Samadi
Position
Psychiatrist , Fellowship of Psychosomatic Medicine
Latest degree
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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

Not applicable

Data Dictionary

Not applicable