Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Perioperative and Postoperative effects of Duloxetine in reducing postoperative pain in patients with spinal stenosis

Protocol summary

Study aim
Evaluation of the effect of duloxetine before and after surgery in reducing the vas score of patients after surgery compared to the control group in Shah Vali Hospital in Yazd in patients undergoing spinal stenosis surgery

Design
Clinical trial with intervention and control groups with parallel groups of double-blind randomized phase 2 on 64 patients.

Settings and conduct
shahvali hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria for all patients with spinal canal stenosis and exclusion criteria for drug allergy and abnormal liver and kidney function test and use of opioids, gaba pentin and pregabalin for more than three months and pregnant women and patients with Psychiatry disorders and seizure disorders

Intervention groups
samples are divided into two groups. The intervention group will receive 60 mg of oral duloxetine daily for 1 day before surgery, 60 mg daily from the day of surgery to the first day after surgery (total for 3 days). The control group will receive a placebo with the same schedule and time.

Main outcome variables
Time required for analgesia, pain intensity, type of medication used

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210124050130N1**
Registration date: **2021-08-07, 1400/05/16**
Registration timing: **registered_while_recruiting**
Last update: **2021-08-07, 1400/05/16**
Update count: **0**

Registration date
2021-08-07, 1400/05/16

Registrant information

Name
Mitra Shahriarypoor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3822 5260

Email address
mitrashahriary143@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-26, 1400/04/05

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Perioperative and Postoperative effects of Duloxetine in reducing postoperative pain in patients with spinal stenosis

Public title
evaluation of the effect of duloxetine in reducing pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all patients with spinal stenosis

Exclusion criteria:

Allergy to the test drug Abnormal liver and kidney function test Use of opioids, gabapentin and pregabalin for more than three months

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by simple randomization method. How to select people and place them in dual groups will be random. Thus, after confirming the necessary conditions to enter the study, patients will be selected sequentially, the first patient in the first group, the second patient in the second group. In the same way, again, the groups will take each patient until the desired limit is reached, the number of samples in the intervention and control groups is equal.

Blinding (investigator's opinion)

Double blinded

Blinding description

The studied drugs were prepared by a neurosurgeon who did not participate in the project later and were stored in sealed envelopes on which the patient code was written. The envelopes were in the neurosurgery ward one day before surgery; Day of surgery; day after surgery; It is opened by a neurosurgeon who does not know the type of drug and the group in which the patient is placed. Nurses and patients are also unaware of the type of drug and the patient group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of azad yazd university of medical sciences

Street address

shohadaye gomnam blvd

City

yazd

Province

Yazd

Postal code

8915813135

Approval date

2021-05-16, 1400/02/26

Ethics committee reference number

IR.IAU.YAZD.REC.1400.004

Health conditions studied

1

Description of health condition studied

Evaluation of the Perioperative and Postoperative effects of Duloxetine in reducing postoperative pain in patients with spinal stenosis

ICD-10 code

M48.0

ICD-10 code description

Spinal stenosis

Primary outcomes

1

Description

numeric rating scale according to visual analogue scale

Timepoint

visual analogue scale before surgery and 2 hours after surgery and 24 hours after surgery

Method of measurement

by visual analogue scale criterion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive 60 mg of oral duloxetine daily for 1 day before surgery, 60 mg daily from the day of surgery to the first day after surgery (total 3 days).

Category

Treatment - Drugs

2

Description

Control group: placebo one day before surgery;day of surgery;one day after surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahvali Hospital
Full name of responsible person
Hamid Hobobati
Street address
Shohadaye Gomnam Blvd
City
Yazd
Province
Yazd
Postal code
89195155
Phone
+98 35 3821 1091
Email
Shahvali.Hospital93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ahmad Shajari
Street address
Shohadaye gomnam blvd
City
Yazd
Province
Yazd
Postal code
8915813135
Phone
+98 35 3821 0540
Email
ethics.iauyazdmedical@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University
Full name of responsible person
Mitra Shahriary poor
Position
Medical intern
Latest degree
A Level or less
Other areas of specialty/work
Others
Street address
Shahid ghandi Blvd
City
Yazd
Province
Yazd
Postal code
8915877851
Phone
+98 34 4225 7756
Email
mitrashahriary143@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Hamid Hobobati
Position
Neurosurgeon
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Shahid ghandi blvd
City
Yazd
Province
Yazd
Postal code
8915877851
Phone
+98 35 3728 8008
Email
hh1358@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mitra Shahriary poor
Position
Medical intern

Latest degree
A Level or less
Other areas of specialty/work
Others
Street address
Shahid ghandi Blvd
City
Yazd
Province
Yazd
Postal code
8915877851
Phone
+98 34 4225 7756
Email
mitrashahriary143@gmail.com

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