Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of duloxetine at doses of 20, 30, and 60 mg on pain intensity in patients with chronic low back pain aged 40 to 65 years

Protocol summary

Study aim
To compare the effect of duloxetine at daily doses of 20, 30, and 60 mg on pain intensity in patients with chronic low back pain

Design
Randomized, parallel-group, single-blind (assessor-blind), phase 3 clinical trial with 1:1:1 allocation using permuted block randomization. Allocation concealed in sequentially numbered, opaque, sealed envelopes

Settings and conduct
The study is conducted at Imam Ali Clinic, Shahrekord, started in 2026. Participants and the treating physician are not blinded due to identifiable drug doses. The outcome assessor, who measures pain via Visual Analogue Scale (VAS) and records adverse events, remains blinded. Pain is assessed at baseline and every 2 weeks through week 6

Participants/Inclusion and exclusion criteria
Inclusion criteria: chronic low back pain diagnosed by a rheumatologist; discopathy; age 40–65 years; non-pregnant and non-lactating; no psychiatric medication use. Exclusion criteria: confirmed aortic aneurysm; unavailability for follow-up; known hypersensitivity to duloxetine; unwillingness to participate.

Intervention groups
Three groups of 45 patients: Group 1 receives duloxetine 20 mg daily for 6 weeks. Group 2 receives duloxetine 30 mg daily for 6 weeks. Group 3 starts with 20 mg daily in week 1, increasing by 20 mg weekly to reach 60 mg daily by week 3, then continues 60 mg daily through week 6

Main outcome variables
Pain intensity measured by Visual Analogue Scale (VAS, 0–10) at weeks 2, 4, and 6; adverse events.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20260627069967N1**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **prospective**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date
2026-06-29, 1405/04/08

Registrant information

Name
Sajjad Radfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 4263 6416
Email address
sajjadradfar75@gmail.com

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-07-23, 1405/05/01
Expected recruitment end date
2028-05-21, 1407/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of duloxetine at doses of 20, 30, and 60 mg on pain intensity in patients with chronic low back pain aged 40 to 65 years

Public title

Effect of Different Doses of Duloxetine on Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic low back pain diagnosed by a rheumatologist Discopathy (degenerative disc, disc protrusion or herniation) Exclusion of other specific causes of low back pain (referred pain, recent trauma, fractures) confirmed by a rheumatologist Age 40–65 years Non-pregnant and non-lactating No current use of psychiatric medications

Exclusion criteria:

Confirmed aortic aneurysm Unavailability for follow-up visits Known hypersensitivity to duloxetine Unwillingness to participate

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with a 1:1:1 allocation ratio. Block sizes of 6 and 9 are used randomly. The unit of randomization is the individual patient. No stratification is applied. The random sequence is generated using Random Allocation Software (version 1.0). For allocation concealment, the assignment sequence is prepared by an independent colleague not involved in the intervention or outcome assessment, and placed in sequentially numbered, opaque, sealed envelopes (SNOSE). After obtaining informed consent and completing baseline assessments, the corresponding envelope is opened to reveal the group assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, with the drug dose clearly identifiable on the medication packaging, participants and the treating physician (principal investigator responsible for prescribing and patient visits) are not blinded to group assignment. All patients are informed that they are participating in a clinical trial and will receive one of three doses of duloxetine, and written informed consent is obtained. The outcome assessor (measuring pain intensity via VAS and recording adverse events) is a trained independent colleague not involved in patient care, who remains blinded to treatment allocation. To maintain assessor blinding, patients are instructed not to disclose their dose during assessment sessions. Group allocation is not recorded on assessment forms or case report files used by the assessor; groups are identified only by a unique code that does not reveal the dose. After data collection, the database is anonymized by another person and handed over to the statistician for analysis without group identifiers. No formal Data Safety and Monitoring Board (DSMB) has been established, but study progress and serious adverse events are continuously monitored by the supervising professors. The authors drafting the manuscript will remain blinded to group allocation until the database is locked and the code is broken.

Placebo

Not used

Assignment

Parallel

Other design features

This is a randomized, parallel-group, single-blind (assessor-blind) clinical trial with three treatment arms. Because the prescribed dose is identifiable on the drug label, blinding of participants and the prescribing physician is not feasible; only the outcome assessor remains blinded to group allocation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahrekord University of Medical Sciences

Street address

Kashani St, Shahrekord University of Medical Sciences, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2024-06-16, 1403/03/27

Ethics committee reference number

IR.SKUMS.MED.REC.1405.077

Health conditions studied

1

Description of health condition studied

Chronic Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description
Pain intensity score measured by Visual Analogue Scale
Timepoint
Before intervention (baseline) and weeks 2, 4, and 6 after treatment initiation
Method of measurement
Visual Analogue Scale: a 10-centimeter line where 0 represents "no pain" and 10 represents "worst possible pain"; the patient indicates pain intensity on the line. Standardized tool with confirmed validity and reliability.

Secondary outcomes

1

Description
Incidence of any adverse events including nausea, dizziness, somnolence, fatigue, sweating, dry mouth, constipation, and diarrhea
Timepoint
Weeks 2, 4, and 6 after treatment initiation
Method of measurement
Direct patient interview at each visit and recording of any experienced adverse events on an adverse event checklist

Intervention groups

1

Description
Intervention group: Duloxetine hydrochloride (manufactured by Actoverco) at a dose of 30 mg, one oral capsule daily, for 6 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Duloxetine hydrochloride (manufactured by Actoverco) starting at 20 mg once daily in week 1, increasing to 40 mg once daily in week 2, and then 60 mg once daily from week 3 through week 6. All capsules are taken orally once daily
Category
Treatment - Drugs

3

Description
Control group: Duloxetine hydrochloride (manufactured by Actoverco) at a dose of 20 mg, one oral capsule daily, for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali Clinic
Full name of responsible person
Sajad Radfar
Street address
Shariati St, Shahrekord, Iran.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3333 0061
Email
Sajjadradfar75@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Shahin Asgari Savadjani
Street address
Kashani St, Shahrekord, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3333 0061
Email
st_asgari.sh@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Sajjad Radfar

Position
Medical resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
No.41, west Molavi Ave., Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 31 4263 6416

Fax

Email
Sajjadradfar75@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Sajjad Radfar

Position
Medical resident

Latest degree
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Other areas of specialty/work
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Postal code
8815713471

Phone
+98 31 4263 6416

Fax

Email
Sajjadradfar75@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Sajjad Radfar

Position
Medical resident

Latest degree
Medical doctor

Other areas of specialty/work
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Fax

Email
Sajjadradfar75@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
Not applicable

Data Dictionary
Not applicable