Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Duloxetine Alone and in Combination with Bupropion on Cognitive Symptoms and Depression in Patients with Fibromyalgia

Protocol summary

Study aim

Comparison of the effects of duloxetine alone versus duloxetine combined with bupropion on cognitive symptoms and depression in patients with fibromyalgia.

Design

This study is a randomized controlled clinical trial (RCT) with parallel groups that is conducted on patients with fibromyalgia referring to Imam Khomeini Clinic, Razi Hospital, Psychosomatic Clinic. The statistical population includes patients who, based on the diagnosis of the treating physician, start treatment with duloxetine (at a dose of 20 to 60 mg per day). Patients' symptoms are assessed using the following standard tools in two stages: • Before the intervention begins (baseline). • End of the 12th week (post-intervention).

Settings and conduct

Eligible patients are randomly divided (using a random number table) by an independent researcher into two groups: 1. Intervention group: treatment with duloxetine bupropion at a dose of 150 mg per day. 2. Control group: treatment with duloxetine alone (without bupropion).

Participants/Inclusion and exclusion criteria

Adults with a confirmed diagnosis of fibromyalgia based on ACR criteria and meeting the minimum required scores on pain and depression scales.

Intervention groups

For the first group, duloxetine at a variable dosage (20 to 60 mg) plus bupropion (150 mg daily) will be prescribed; for the second group, duloxetine capsules will be prescribed at a variable dosage.

Main outcome variables

Hospital Anxiety and Depression Scale (HADS): To measure depressive symptoms. Metamemory Questionnaire (MMQ): To assess cognitive symptoms (metamemory). Visual Visual Analogue Scale (VAS): To measure pain intensity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260819070731N1**
Registration date: **2026-09-08, 1405/06/17**
Registration timing: **prospective**

Last update: **2026-09-08, 1405/06/17**
Update count: **0**

Registration date

2026-09-08, 1405/06/17

Registrant information

Name

Sara Farhang

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effects of Duloxetine Alone and in Combination with Bupropion on Cognitive Symptoms and Depression in Patients with Fibromyalgia

Public title
Duloxetine Alone and in Combination with Bupropion in Patients with Fibromyalgia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 65 years Definitive diagnosis of fibromyalgia based on ACR criteria Meeting the minimum required scores on pain and depression scales (to ensure the presence of assessable symptoms) o changes to other pharmacological or non-pharmacological treatments over the past 3 months Written informed consent to participate in the study

Exclusion criteria:
Presence of major comorbid psychiatric disorders (e.g., psychosis, bipolar disorder, substance abuse) Presence of comorbid physical conditions that could explain cognitive symptoms or pain (e.g., uncontrolled hypothyroidism, multiple sclerosis) Hypersensitivity to duloxetine or bupropion Pregnancy or breastfeeding Presence of unstable medical conditions likely requiring immediate intervention Pain symptoms associated with conditions other than fibromyalgia that might interfere with the interpretation of results Current or past confirmed diagnosis of rheumatoid arthritis, inflammatory arthritis, or other autoimmune diseases Severe liver disease History of using medications that affect cognition (e.g., acetylcholinesterase inhibitors and anticonvulsants) Patient intolerance to the prescribed medication or development of adverse effects (bupropion or duloxetine)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a random number table In this method, each participant in the study is assigned a number (from 1 to 40; depending on the sample size) and a subset of the population is randomly selected using a random number table. Even numbers are assigned to the duloxetine alone group and odd numbers are assigned to the duloxetine plus bupropion group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted in a double-blind manner. Following randomization, bupropion and placebo capsules, which will be identical in appearance, color, packaging, and administration schedule, will be provided to participants in sealed and coded packages for concomitant use with duloxetine. The allocation codes will be maintained by an individual who is independent of the assessment and data collection processes. Neither the participants nor the researcher responsible for clinical assessments and data collection will be aware of the treatment allocation. In addition, the data analyst will remain blinded to the allocation codes until completion of the statistical analysis and finalization of the results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
دانشگاه علوم پزشکی تبریز (کمیته اخلاق در پژوهش)

Street address
Golgasht

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Tabriz

Province
East Azarbaijan

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5166614766

Approval date
2026-06-08, 1405/03/18

Ethics committee reference number
IR.TBZMED.REC.1405.163

Health conditions studied

1

Description of health condition studied
Fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description

Hospital Anxiety and Depression Scale

Timepoint

Before the start of the intervention and at the end of the twelfth week

Method of measurement

HADS questionnaire

2

Description

Memory test

Timepoint

Before the start of the intervention and at the end of the twelfth week

Method of measurement

MMQ

3

Description

Pain

Timepoint

Before the start of the intervention and at the end of the twelfth week

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with duloxetine (with a dose of 20 to 60 mg per day) + bupropion at a dose of 150 mg per day

Category

Treatment - Drugs

2

Description

Control group: Treatment with duloxetine alone (with a dose of 20 to 60 mg per day)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک امام خمینی

Full name of responsible person

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Sponsors / Funding sources

1

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sara Farhang

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the main outcomes will be reported.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will be available for use in other studies such as review studies.
From where data/document is obtainable
Dr. Sara Farhang, Associate Professor of Psychiatry, Razi Psychiatric University Hospital, El Goli Boulevard, POB 5456 Tabriz, I.R.IRAN. dsfarhang@gmail.com Fax:+98+413+3803353.
What processes are involved for a request to access data/document
Email to correspondence Dr. Sara Farhang, Associate Professor of Psychiatry, Razi Psychiatric University Hospital, El Goli Boulevard, POB 5456 Tabriz, I.R.IRAN. dsfarhang@gmail.com Fax:+98+413+3803353.
Comments