

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Depression and pain improvement in patients with fibromyalgia syndrome with duloxetine or pregabalin: a comparative open labeled study

Protocol summary

Summary

This open labeled RCT research planned in HAZRAT-E-RASOOL hospital rheumatology clinic and executive private clinic, to determine the relation between depression indexes improvement and pain reduction in fibromyalgia patients after duloxetine and pregabalin consumption. The goal of trial is comparison the efficacy of drugs as well as to investigate independent antidepressant role of duloxetine in reducing pain. 70 Fibromyalgia patients between 18 and 65 years old who have not getting duloxetine, Pregabalin and gabapentin or other antidepressants during the 12 weeks before entering the study will enroll to the study. Patients will randomly be assigned equally in two groups of 35. First, demographic information and slightly questionnaires complete and after dolorimetry one group of patients will take 30 mg duloxetine and the other group will receive 75 mg of Pregabalin. A week later, patients will be visited again and in the absence of significant side effects duloxetine dose will be increased to 60 mg and Pregabalin to 150 mg. Patients will be followed 4 weeks and will be visited again at the end of study to gather outcome variables data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626935N1**

Registration date: **2016-07-06, 1395/04/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-06, 1395/04/16

Registrant information

Name

Ali Bidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2202 6576

Email address

bidari.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-05, 1395/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Depression and pain improvement in patients with fibromyalgia syndrome with duloxetine or pregabalin: a comparative open labeled study

Public title

Pregabalin and Duloxetine in fibromyalgia treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: fibromyalgia patients; age between 18 to 65; Exclusion criteria: receiving Duloxetine, Pregabalin and Gabapentin with other antidepressants during the 12 weeks before entering the study; pregnancy or have a plan to become pregnant during the study; underlying rheumatic disease, cancer, and other diseases that can

cause chronic pain which has not been defined in the fibromyalgia syndrome; having a job or duties which need high concentration or alertness; use of MAOI (monoamine oxidase inhibitors) within 14 days before study; chronic liver disease, severe renal failure and uncontrolled narrow-angle glaucoma; history of hypersensitivity to Pregabalin and its components

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Science

Street address

tehran, Hemmat freeway

City

Tehran

Postal code

Approval date

2014-07-21, 1393/04/30

Ethics committee reference number

25371-109861

Health conditions studied

1

Description of health condition studied

Fibromyalgia

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

Primary outcomes

1

Description

Pain

Timepoint

At the begining and 4 weeks after treatment

Method of measurement

FIQ and WPI questionnaire

2

Description

Depression

Timepoint

At the begining and 4 weeks after treatment

Method of measurement

SF-12 and becks questionnaire

Secondary outcomes

1

Description

Drug adverse reactions

Timepoint

1 week after start the drug

Method of measurement

Drug adverse reactions questionnaire

Intervention groups

1

Description

Duloxetine 30 mg once daily and if tolerate increase to 60 mg once daily for 3 next week.

Category

Treatment - Drugs

2

Description

Pregabalin 75 mg once daily and after 1 week if tolerate increase to 75 mg twice daily for 3 next 3 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology clinic of Hazrat Rasool Akram hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Dr Ali Bidari private clinic

Full name of responsible person**Street address****City**

Tehran

3

Recruitment center

Name of recruitment center

Dr Nahid Kianmehr private clinic

Full name of responsible person**Street address****City**

Tehran

4

Recruitment center

Name of recruitment center

Dr Banafsheh Ghavidel private clinic

Full name of responsible person**Street address****City**

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Iran University of Medical Sciences

Full name of responsible person

Dr Javad Mousavi

Street address

Hemmat freeway

City

Tehran

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

Yes

Title of funding source

Vice Chancellor for Research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Dr. Shahrzad Rahmani

Position

Rheumatologist

Other areas of specialty/work**Street address**

Firoozgar Hospital

City

Tehran

Postal code**Phone**

+98 21 4438 7425

Fax**Email**

shz_rahmani@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Science

Full name of responsible person

Dr. Ali Bidari

Position

Rheumatologist

Other areas of specialty/work**Street address**

Hazrat Rasool Akram Hospital

City

Tehran

Postal code**Phone**

+98 21 86701

Fax**Email**

bidari.a@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Science

Full name of responsible person

Dr. Shahrzad Rahmani

Position

Rheumatologist

Other areas of specialty/work**Street address**

Valiasr square, Firoozgar Hospital

City

Tehran

Postal code**Phone****Fax**

Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty