Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

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

Protocol summary

Summary

This open labled RCT research planned in HAZRAT-E-RASOOL hospital rheumatology clinic and executive private clinic, to determine the relation between depression indexes improvment and pain reduction in fibromyalgia patients after duloxetin and pregabalin consumption. The goal of trial is comparison the efficacy of drugs as well as to investigate independent anti-depressant role of duloxetin in reducing pain. 70 Fibromyalgia patients between 18 and 65 years old who have not getting duloxetin, 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 sightly questionnaires complete and after dulorimetry one group of patients will take 30 mg duloxetin 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 duloxetin 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 duloxetin or pregsbalin: a comparative open labeled study

Public title

Pregabalin and Duloxetin 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 questionaire

2

Description
Depression

Timepoint
At the begining and 4 weeks after treatment

Method of measurement
SF-12 and becks questionaire

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
Duloxetin 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
Rheumathology 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
Rheumathologist
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
Rheumathologist
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