Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of duloxetine and pregabalin Effects on invalidation score and depression in Patients with Fibromyalgia.

Protocol summary

Study aim
The goal of the study is comparison of duloxetine and pregabalin effects on invalidation score and depression in patients with fibromyalgia.

Design
open-label randomized clinical trial

Settings and conduct
This study will be conducted in subspecialty clinic of Razi hospital of Rasht under a rheumatology specialist. Diagnosis of patients is based on ACR 2010. All patients will complete and sign informed consent, then the patients will be randomized into two groups using random blocks of allocation. Patients will complete the inventories of illness invalidation, beck depression and FIQR in starting of the study and 1 month later. All data will be analyzed by special statistical softwares.

Participants/Inclusion and exclusion criteria
Inclusion criteria:female,patients must meet the American College of Rheumatology criteria for fibromyalgia(ACR2010) and rheumatologist confirm fibromyalgia diagnosis. Exclusion criteria:age younger than 18 or older than 65 years old, pregnancy or plans to become pregnant, taking MAOIs, chronic disease, history of sensitivity to Pregabalin and Duloxetine .

Intervention groups
Two groups of fibromyalgia patients: one group receive duloxetine capsules 30 mg daily initially, and finally 60 mg daily from Lilly's Pharmaceutical Company, and the other group receive pregabalin 75 mg initially and finally 150 mg daily from Pfizer company.

Main outcome variables
Invalidation in patient with fibromyalgia;Beck depression score in patient with fibromyalgia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181113041646N1**
Registration date: **2019-11-05, 1398/08/14**
Registration timing: **prospective**

Last update: **2019-11-05, 1398/08/14**
Update count: **0**

Registration date
2019-11-05, 1398/08/14

Registrant information

Name
Ashkan Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3467 2363

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ashkan96shamami@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of duloxetine and pregabalin Effects on invalidation score and depression in Patients with Fibromyalgia.

Public title

Effect of duloxetine and pregabalin on invalidation in fibromyalgia.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female . Patients must meet the American College of Rheumatology criteria for fibromyalgia (ACR2010). A rheumatologist confirm diagnosis of fibromyalgia.

Exclusion criteria:
Age younger than 18 or older than 65 years old Pregnancy . Taking MAOIs (monoamine oxidase inhibitors) in the 14 days before study. Cases of chronic liver disease, severe renal failure and uncontrolled narrow angle glaucoma. History of sensitivity to Pregabalin and its components. History of sensitivity to Duloxetine and its components.

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized allocation with block method by statistical software .

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
Ethics committee of guilan university of medical sciences

Street address
Rasht,Namjoo avenue,shahid siadati street,infront of 17shahrivar hospital

City
Rasht

Province
Guilan

Postal code
4144895655

Approval date
2019-07-21, 1398/04/30

Ethics committee reference number
IR.GUMS.REC.1398.208

Health conditions studied

1

Description of health condition studied
Invalidation in patient with fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Invalidation in patient with fibromyalgia.

Timepoint
Before starting the study, then one month after taking medication.

Method of measurement
Illness invalidation questionnaire.

2

Description
Depression score in Beck depression inventory.

Timepoint
Before starting the study,then one month after taking medication.

Method of measurement
Beck depression questionnaire.

Secondary outcomes

1

Description
severity of disease

Timepoint
Before starting the study, then one month after taking medication.

Method of measurement
FIQR Questionnaire

Intervention groups

1

Description
Intervention group: Group one includes patients diagnosed with fibromyalgia receiving duloxetine with the initial dose of 30 mg daily in form of oral capsule for one month. The dose will be increased up to 60 mg daily after 1 week depending on tolerance. Duloxetine (Cymbalta (Lilly company – USA) is a serotonine and

norepinephrine reuptake inhibitor with formula of C18H19NOS. It can be administered either before or after meals.

Category

Treatment - Drugs

2

Description

Intervention group2: Group two includes patients diagnosed with fibromyalgia receiving Pregabalin capsule orally with the initial dose of 75 mg daily for one month .the dose will be increased up to 150 mg daily after 1week depending on tolerance.. Pregabalin (Lyrica (Pfizer – USA))has the formula of C8H17NO2 and its active metabolite is N-methyl pregabalin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital clinic

Full name of responsible person

Banafsheh gavidel parsa

Street address

Esteghamat avenue.,razi clinic tower

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Banafshe Ghavidel parsa

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Position

Medical student

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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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
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