

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Sep 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)

###### Phone

+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 C<sub>18</sub>H<sub>19</sub>NOS. 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 C<sub>8</sub>H<sub>17</sub>NO<sub>2</sub> 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Shadman nemati

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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 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