

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Evaluation and comparison of side effects of Pregabalin and Gabapentin in patients with Psychiatric disorders.

Protocol summary

Study aim

Evaluation & comparison of the side effects of Pregabalin & Gabapentin in patients with psychiatric disorders.

Design

Randomized clinical trial with parallel groups.

Settings and conduct

The research is performed in patients referring to the psychology department of Taleghani hospital and Imam Hossein Hospital affiliated to Shahid Beheshti University of Medical Sciences based on the standard questionnaire. Patients are divided into two groups receiving Pregabalin and Gabapentin, and side effects are assessed at 1-month intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women or men with anxiety or depression disorders aged 18 to 65 years; consenting to enter the research. Their medication can include sertraline 50 to 100 mg, citalopram 20 to 40 mg, or citalopram 10 mg. Exclusion criteria: Refusing to complete the questionnaire. The person getting divorced or menopause. Taking any other medication or dosage other than the above-mentioned dose. Pregnancy or lactation. The person having substance abuse during the study. being allergic to pregabalin and gabapentin.

Intervention groups

Intervention Group 1: Pregabalin recipients. Intervention group 2: Gabapentin recipients.

Main outcome variables

The incidence of the side effects of the two drugs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N23**

Registration date: **2021-09-01, 1400/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-01, 1400/06/10**

Update count: **0**

Registration date

2021-09-01, 1400/06/10

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8887 3704

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-13, 1400/05/22

Expected recruitment end date

2021-08-13, 1400/05/22

Actual recruitment start date

2021-08-14, 1400/05/23

Actual recruitment end date

2022-01-13, 1400/10/23

Trial completion date

2022-03-16, 1400/12/25

Scientific title

Evaluation and comparison of side effects of Pregabalin and Gabapentin in patients with Psychiatric disorders.

Public title

Evaluation and comparison of side effects of Pregabalin and Gabapentin in patients with Psychiatric disorders.

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 65 years old. Suffering from depression or anxiety. Taking Sertraline (50-100mg) or Citalopram (20-40mg) or Escitalopram (10mg). Consent to enter the research. Be married.

Exclusion criteria:

Refusing to fill the questionnaire. Getting divorced or reaching menopause Taking medications other than those listed. Pregnancy or lactation. Having substance abuse during the study. Being allergic to Pregabalin or Gabapentin.

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

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

Ethics committee of Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Street address

The SBMU school of pharmacy, Valiasr St., Niayesh cross section, Tehran

City

Tehran

Province

Tehran

Postal code

1991953381

Approval date

2019-11-10, 1398/08/19

Ethics committee reference number

1398.222.IR.SBMU.PHARMACY.REC

Health conditions studied

1

Description of health condition studied

Anxiety disorder

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

Depressive disorder

ICD-10 code

F06.32

ICD-10 code description

Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

Sexual Dysfunctions

Timepoint

One Month

Method of measurement

The International Index of Erectile function Questionnaire; The Female Sexual Function Index Questionnaire

2

Description

Drowsiness

Timepoint

One Month

Method of measurement

Questionnaire

3

Description

Dizziness

Timepoint

One Month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The first group will receive 75 to

150 mg of oral pregabalin per day.

Category

Treatment - Drugs

2

Description

Second intervention group: Patients in this group will receive 100 to 600 mg of oral gabapentin per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Psychology, Taleghani Hospital

Full name of responsible person

Azadeh Mazaheri

Street address

Daneshjoo Boulevard, Arabi Street, Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti University of Medical Sciences, Erabi St, Shahid Chamran Highway, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Maria Tavakoli Ardakani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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