

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigation and Comparison of Quetiapine and Trazodone Effects on Sleep quality and Depression Severity in Patients with major depressive disorder

Protocol summary

Study aim

Determining and comparing the effects of Quetiapine and Trazadone drugs on sleep quality and severity of depression in patients with major depressive disorder

Design

A clinical trial with a control group, with parallel groups, double-blind/randomized/phase 3 on 105 patients/ rand function software of this year's software was used for randomization.

Settings and conduct

The research population of the present study is a group of people suffering from depression disorder (depression means moderate to high depression) who, taking into account the entry and exit criteria, were selected from among the clients to Shahid Muffateh Yasouj Outpatient Clinic and entered knowingly by obtaining a written consent form. will be investigated. Sertraline (SSRI) drug will be given as the main drug in order to maintain and observe ethical principles. The first group of patients will be treated with quetiapine and the second group with trazodone, both of which will be placed in capsules of the same shape.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from a depressive disorder according to DSM-V criteria and a psychiatrist confirming the diagnosis and having a minimum score of 20 on the Hamilton Depression Scale; Not taking other drugs to control sleep; Not suffering from cardiovascular diseases, kidney, diabetes; Informed consent to participate in the study

Intervention groups

105 patients with depression will be randomly selected and randomization in the present study will be done using sealed envelopes. Patients will be randomly divided into three groups receiving Trazadone, group receiving Quetiapine and control group. The researcher, the person responsible for data collection and the person

responsible for the statistical analysis of the data, as well as the patient, will remain unaware of their group until the end of the study

Main outcome variables

Sleep quality and severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231129060218N1**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

Registration date

2023-12-25, 1402/10/04

Registrant information

Name

Zahra Rahami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7251

Email address

zahra.rahami@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-29, 1402/10/08

Expected recruitment end date

2024-02-14, 1402/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and Comparison of Quetiapine and Trazodone Effects on Sleep quality and Depression Severity in Patients with major depressive disorder

Public title

Quetiapine and Trazodone Effects on Sleep quality and Depression Severity in Patients with depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient who suffering major depressive disorder according to DSM _V criteria with minimum score 20 on the hamilton depression scale .not taking other drugs to control sleepi Not suffering from cardiovascular disease. Kidney. Diabetes Not taking other drugs to control Informed constant to participate in the study

Exclusion criteria:

No depression disorder (MDD) Suffering from cardiovascular disease Suffering from kidney . Diabetes disease Dissatisfaction of the patient

AgeFrom **17 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **105****Randomization (investigator's opinion)**

Randomized

Randomization description

To create a simple random sequence from randomization on the web (www.graphpad.com) and to hide the random allocation, the method of closed envelopes will be used, a number of envelopes, prepared and inside each of the In the letters, the relevant drugs are placed. Finally, the lid of the envelope is glued and delivered to the participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient receives the medicine in a sealed envelope witch is coded Coding is done by one of the colleagues of the project and the patients are blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of yasuj university of medical science

Street address

Yasuj University Medical Science, Saheli street

City

Yasuj

Province

Kohgilouyeh-va-Boyrhmad

Postal code

7591846667

Approval date

2023-10-11, 1402/07/19

Ethics committee reference number

IR.YUMS.REC.1402.106

Health conditions studied**1****Description of health condition studied**

Major depressive disorder

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Depression score in Hamilton questionnaire

Timepoint

The beginning of the study and 15 and 30 days after start of the medicine

Method of measurement

Hamilton questionnaire

Secondary outcomes**1****Description**

Severity of depression

Timepoint

The beginning of the study and 15 and 30 days after start of the medicine

Method of measurement

Hamilton questionnaire

Intervention groups

1

Description

Intervention group: first: use Trazadone drug

Category

Treatment - Drugs

2

Description

Intervention group: second; use Quetiapine drug

Category

Treatment - Drugs

3

Description

Control group: third; use placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh Clinic

Full name of responsible person

Zahra Rahami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed amin hoseini motlagh

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Zahra Rahami

Position

Internist

Latest degree

Specialist

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

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