

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effectiveness of three drugs agomelatine, bupropion and sertraline in the treatment of non psychotic major depressive disorder: A randomized double blind clinical trial

Protocol summary

Study aim

Determining the effectiveness of three drugs agomelatine, bupropion and sertraline in the treatment of non-psychotic major depressive disorder

Design

Clinical trial without control group, with parallel groups, double-blind, randomized, 90 patients with 6 block size will be randomly assigned to three groups of 33 people.

Settings and conduct

The study population was patients aged 20-60 years referred to a psychiatric clinic and patients admitted to the psychiatric ward. Patients will be randomly divided into 3 intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20-60 years; Major Depressive Disorder (Based on the diagnosis of a psychiatrist and a psychiatric assistant with a structured clinical interview based on the DSM-5) Exclusion criteria: substance abuse; Hypothyroidism; Severe anemia; Pregnancy and lactation; Epilepsy; Mental retardation

Intervention groups

Intervention group 1: Patients in the agomelatine group (Tadbir Kalay Jam Company) will initially receive 25 mg of the drug daily at bedtime for two weeks, and patients who do not show improvement with 25 mg per day will be increased to 50 mg per day. (Depending on the patient's response, it is possible to increase the dose to a maximum of 50 mg). Intervention group 2: Patients in the sertraline group (Sobhan company) will receive 50 mg of the drug every morning (depending on the patient's response, the dose can be increased to a maximum of 200 mg). Intervention group 3: Patients in the bupropion group (Abidi company) will receive 75 mg twice a day (depending on the patient's response, the dose can be increased to a maximum of 450 mg).

Main outcome variables

patient's depressive condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043700N4**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Romina Hamzehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of three drugs agomelatine, bupropion and sertraline in the treatment of non psychotic major depressive disorder: A randomized double blind clinical trial

Public title

Efficacy of three drugs agomelatine, bupropion and sertraline in the treatment of major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-60 years Major Depressive Disorder (Based on the diagnosis of a psychiatrist and a psychiatric assistant with a structured clinical interview based on the DSM-5)

Exclusion criteria:

Drug abuse Hypothyroidism Severe anemia Pregnancy and lactation Epilepsy Mental retardation

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to three groups of 30 using 6 blocks in a ratio of 1: 1: 1. Randomization will be performed using a randomization table (computer randomization program). The randomization table will be created by a statistical expert and will be provided to the researchers. The patient and the researcher (evaluator) will not know how to classify and the type of drug received and only the treating physician is aware of the type of drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

Agomelatine (Tadmir Kalay Jam Company), Sertraline (Sobhan Company) and Bupropion (Obaidi Company) will be poured into separate capsules in the form of crushed tablets. The shape, color, size and packaging of all medicines are exactly the same. Consecutive opaque numbered envelopes were used to conceal the allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

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Mazandaran

Postal code

4717647745

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.086

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

patient's depressive condition

Timepoint

Before the intervention (first visit), end of the second week (second visit), end of the fourth week (third visit), end of the eighth week (fourth visit)

Method of measurement

Hamilton Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Patients in the agomelatine group (Tadmir Kalay Jam Company) will initially receive 25 mg of the drug daily at bedtime for two weeks, and patients who do not show improvement with 25 mg per day will be increased to 50 mg per day. (Depending on the patient's response, it is possible to increase the dose to a maximum of 50 mg).

Category

Treatment - Drugs

2**Description**

Intervention group2: Patients in the sertraline group (Sobhan company) will receive 50 mg of the drug every morning (depending on the patient's response, the dose can be increased to a maximum of 200 mg).

Category

Treatment - Drugs

3**Description**

Intervention group3: Patients in the bupropion group (Abidi company) will receive 75 mg twice a day (depending on the patient's response, the dose can be increased to a maximum of 450 mg).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yahyanezhed Hospital

Full name of responsible person

Romina Hamzhepour

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Romina Hamzhepour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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