

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Lumateperone as adjuvant therapy to sertraline in major depressive disorder: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

Investigating the effect of Lumateperone as adjuvant therapy to sertraline in major depressive disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients with MDD attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Based on DSM-V have a diagnosis of major depression (MDD) and their minimum severity of depression based on HDRS is 19 Age between 18-65.
Exclusion criteria: Any other mental disorder in another axis - Serious suicidal thoughts (<2 in suicidal HDRS section) - Psychosis - History of ECT in recent two months - History of mania and hypomania - Thyroid dysfunctions - History of cardiovascular disease - Diabetes - Autoimmune disorders - Presence of active infection - Neurologic disorders like epilepsy and Alzheimer's disease - Liver disease - Kidney disease - Pregnant or lactating women.

Intervention groups

Intervention group received sertraline at a dose of 100 mg / day, and Lumateperone at a dose of 42 mg / day, and the control group received sertraline at a dose of 100 mg / day and placebo. Patients at weeks 0, 2, 4, and 8 will be evaluated by the HDRS. Neuropsychiatric assessments are applied at baseline (first visit) and final (eighth week). Finally, side effects at each visit are assessed using a 25-item questionnaire (Systematic Assessment for Treatment Emergent Effects).

Main outcome variables

Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N141**

Registration date: **2022-03-01, 1400/12/10**

Registration timing: **prospective**

Last update: **2022-03-01, 1400/12/10**

Update count: **0**

Registration date

2022-03-01, 1400/12/10

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Lumateperone as adjuvant therapy to sertraline in major depressive disorder: A randomized double blind and

placebo controlled clinical trial

Public title

Lumateperone as adjuvant therapy for major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Based on DSM-V have a diagnosis of major depression (MDD) and their minimum severity of depression based on HDRS is 19 Age between 18-65

Exclusion criteria:

Any other mental disorder in another axis Serious suicidal thoughts (<2 in suicidal HDRS section) Psychosis History of ECT in recent two months History of mania and hypomania Thyroid dysfunctions History of cardiovascular disease Diabetes Autoimmune disorders Presence of active infection Neurologic disorders like epilepsy and Alzheimer's disease Liver disease Kidney disease Pregnant or lactating women

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.TUMS.DDRI.REC.1400.048

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Severity of depression

Timepoint

Weeks 0 - 4 - 8

Method of measurement

by Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received sertraline at a dose of 100 mg / day, and Lumateperone at a dose of 42 mg / day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: received sertraline at a dose of 100 mg / day and placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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1333715914

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr..Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Qhods St.,
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afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2022 to 2027

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments