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 Hamiltion 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

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Email

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., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8898 7381

Email

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

Street address

Roozbeh Hospital, South Kargar Street, Tehran

City

Tehran

Province

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Person responsible for updating data

Contact

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City
Tehran
Province
Tehran
Postal code
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Phone
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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