Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Tipepidine as adjuvant therapt in major depression: a randomised controlled trial

Protocol summary

Study aim
The objective of this study is to assess the efficacy of pentoxifylline in the treatment of MDD
Design
Randomized double blind and placebo-controlled clinical trial
Settings and conduct
The study will be conducted among adults with major depressive disorder attending Roozbeh Hospital.
Participants/Inclusion and exclusion criteria
Inclusion criteria: presence of Major Depressive Disorder based on DSM-5 criteria; baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 19.
Exclusion criteria: presence of psychosis, any other mental disorder; presence of hypothyroidism or cardiovascular problems; pregnancy or nursing women; receiving ECT during last two months, substance use, receiving any other psychotropic medication
Intervention groups
The participants will be randomly allocated into two groups. Intervention group(25 persons) will receive tipipedine (30 mg BID) and citalopram (40 mg per day) and control group (25 persons) will receive placebo plus citalopram (40 mg per day) for 6 weeks.
Main outcome variables
Severity of depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090117001556N122**
Registration date: **2019-10-19, 1398/07/27**
Registration timing: **prospective**

Last update: **2019-10-19, 1398/07/27**
Update count: **0**

Registration date
2019-10-19, 1398/07/27

Registrant information
Name
Shahin Akhondzadeh
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Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-31, 1398/08/09
Expected recruitment end date
2021-09-21, 1400/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Tipepidine as adjuvant therapt in major depression: a randomised controlled trial

Public title
Tipepidine as adjuvant therapt in major depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of Major Depressive Disorder based on DSM-5

criteria Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 19

Exclusion criteria:

Presence of psychosis Any other mental disorder Hypothyroidism Cardiovascular disease Pregnancy or nursing women receiving ECT during last two months substance use receiving any other psychotropic medications

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permuted block

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome raters will be blind regarding grouping

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

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Postal code

1417653761

Approval date

2019-10-03, 1398/07/11

Ethics committee reference number

IR.TUMS.VCR.REC.1398.541

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline and weeks 2,4 and 6

Method of measurement

by Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: tablet citalopram 40 mg/day plus Capsule tipipedine 30 mg BID as intervention group for 6 weeks

Category

Treatment - Drugs

2

Description

Intervention group: tablet citalopram 40 mg/day plus placebo as control group for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiaty Hospital

Full name of responsible person

Dr. Ahmad Ali Noorbala

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South Kargar Street

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1333715914

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences,
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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
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
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Position
Professor of clinical psychopharmacology
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Person responsible for updating data

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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
No - There is not 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 2021 to 2026
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
by citing the resourse
From where data/document is obtainable
Professor Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments