

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 tipepidine (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

###### 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

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**

Tehran

**Province**

Tehran

**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 Hamilton 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 Psychiatry Hospital

**Full name of responsible person**

Dr. Ahmad Ali Noorbala

**Street address**

South Kargar Street

**City**

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1333715914

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences,  
**Full name of responsible person**  
Dr. Mohammad Ali Sahraian  
**Street address**  
Keshavarz Blvd  
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msahrai@tums.ac.ir  
**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**  
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  
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## Person responsible for scientific inquiries

#### Contact

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**Position**  
Professor of clinical psychopharmacology  
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## Person responsible for updating data

#### Contact

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Tehran University of Medical Sciences  
**Full name of responsible person**  
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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 resource

**From where data/document is obtainable**

Professor Shahin Akhondzadeh

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

by E mail

**Comments**