# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluating the effectiveness of citalopram and sertraline in the treatment of depression with respect to the level of BDNF, IL-6, and cortisol in men and women with major depressive disorder: A randomized double-blinded clinical trial

## Protocol summary

**Study aim**
Investigating the efficacy of citalopram and sertraline in depression according to BDNF, IL-6, and cortisol levels
**Design**
Randomized double blind clinical trial
**Settings and conduct**
This study will be performed on patients attending Roozbeh Hospital
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age between 18-60 years old - Based on DSM-V have a diagnosis of major depression (MDD) and their minimum severity of depression based on HDRS is 19. 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**
Control group: women and men with major depressive disorder receiving citalopram (40 mg daily) for six weeks. Intervention group: women and men with major depressive disorder receiving sertraline (100 mg/day) for six weeks.
**Main outcome variables**
Severity of depression

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20090117001556N147**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**
**Registration date**
2022-09-13, 1401/06/22

**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**
2022-11-22, 1401/09/01
**Expected recruitment end date**
2024-11-21, 1403/09/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluating the effectiveness of citalopram and sertraline

in the treatment of depression with respect to the level of BDNF, IL-6, and cortisol in men and women with major depressive disorder: A randomized double-blinded clinical trial

**Public title**
Efficacy of citalopram and sertraline in depression according to BDNF, IL-6, and cortisol levels

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age between 18-60 years old Based on DSM-V have a diagnosis of major depression (MDD) and their minimum severity of depression based on HDRS is 19

**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 **60 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **80**

**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**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of School of Medicine, 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**
2022-06-17, 1401/03/27

**Ethics committee reference number**
IR.TUMS.MEDICINE.REC.1401.452

## Health conditions studied

### 1

**Description of health condition studied**
Depression

**ICD-10 code**
F32.1

**ICD-10 code description**
Major depressive disorder, single episode, moderate

## 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**
Control group: Men and women with major depressive disorder receiving citalopram (40 mg daily) for six weeks.

**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Men and women with major depressive disorder receiving sertraline (100 mg/day) for six weeks.
**Category**
Treatment - Drugs

## 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, Keshavarz Blvd.
**City**
Tehran
**Province**
Tehran
**Postal code**
1417653761
**Phone**
+98 21 5541 2222
**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**
Tehran
**Postal code**
1333715914
**Phone**
+98 21 5541 2222
**Email**
s.akhond@sina.tums.ac.ir

## Person responsible for scientific 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**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr. Shahin Akhondzadeh

**Position**
Professor of clinical psychopharmacology

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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 2023 to 2028

**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**