

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Adalimumab as a adjuvant therapy in modrate to sever MDD in patients with CRP greater than or equal to 3mgr/lit : a double blind and randomized Trial

#### Protocol summary

##### Study aim

The objective of this study is to assess the efficacy of Adalimumab 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, CRP equals or more than 3 mg/lit. Exclusion criteria: presence of psychosis, any other mental disorder; presence of hypothyroidism or cardiovascular problems; pregnancy or nursing women; history of tubercluosis; autoimmune disease; viral hepatitis; HIV; receiving ECT during the last two months; substance use; significant suicidal ideation

##### Intervention groups

The participants will be randomly allocated into two groups. Intervention group(25 persons) will receive Adalimumab (5mg/kg at the begenning) and sertraline ( up to 100 mg per day) for 6 weeks and control group ( 25 persons) will receive placebo at the beginning and sertraline ( up to 100 mg per day) for 6 weeks.

##### Main outcome variables

Severity of depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090117001556N121**

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

2019-11-21, 1398/08/30

##### 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

Adalimumab as a adjuvant therapy in modrate to sever MDD in patients with CRP greater than or equal to 3mgr/lit : a double blind and randomized Trial

##### Public title

Adalimumab as a adjuvant therapy in modrate to sever

MDD

**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 CRP equals or more than 3mg/lit

**Exclusion criteria:**  
Psychotic symptoms Any other mental disorder Hypothyroidism Cardiovascular disease Pregnant or nursing women History of tuberculosis Autoimmune disease Viral hepatitis Chronic or recurrent infections Receiving ECT during the last two months Significant suicidal ideation Substance use HIV

**Age**  
From **18 years** old to **60 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.1398.539

## 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: Adalimumab(iv) 5 mg/kg at the beginning plus tablet sertraline up to100 mg/day for 6 weeks

**Category**

Treatment - Drugs

### 2

**Description**

Control group: placebo(iv) at the beginning plus tablet sertraline up to100 mg/day for 6 weeks

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Roostbeh Psychiatry Hospital

**Full name of responsible person**

Dr. Ahmad Ali Noorbala

**Street address**

South Kargar Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1333715914  
**Phone**  
+98 21 5541 2222  
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s.akhond@sina.tums.ac.ir

## 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**  
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1417653761  
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**Email**  
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**  
Prof. 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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**Province**  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Prof. 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**  
Shahin Akhondzadeh  
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Prof. of Clinical Psychopharmacology  
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**Province**

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**Postal code**

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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**

All data will be distributed through final report

**When the data will become available and for how long**

from 2021 to 2026

**To whom data/document is available**

academic researchers

**Under which criteria data/document could be used**

by email

**From where data/document is obtainable**

Prof Shahin Akhondzadeh

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

s.akhond@sina.tums.ac.ir

**Comments**