

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
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Sponsors / Funding sources

1

Sponsor

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

Ph.D.
Other areas of specialty/work
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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

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