Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial of adjunctive Modafinil treatment in patients with major depression: a double blind and placebo controlled trial.

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of Modafinil as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. Method: 40 adult outpatients who meet the DSM- IV-TR criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 22 will be allocated into two groups. 20 patients will receive Fluoxetine 40 mg/day plus Modafinil 400 mg/day (200 mg bid) (morning and evening) and 20 patients will receive Fluoxetine 40 mg/day plus placebo. Patients will be assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started using Hamilton Rating Scale for Depression(HRSD). Side effects will be also evaluated using a checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902301556N15**
Registration date: **2010-05-24, 1389/03/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-05-24, 1389/03/03

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date

2010-06-05, 1389/03/15

Expected recruitment end date

2010-07-23, 1389/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of adjunctive Modafinil treatment in patients with major depression: a double blind and placebo controlled trial.

Public title

Modafinil and treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of Major Depressive Disorder based on DSM-IV criteria, Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 22,age between 18 to 50 years old . Exclusion criteria: Presence of Psychosis, any diagnosis in Axis I and II, Receiving psychotropic medications, receiving any antidepressants during past one month or ECT in past two months, Presence of hypothyroidism or cardiovascular problems, nursing or pregnant women

Age

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

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Keshavarz Blvd
City
Tehran
Postal code
Approval date
2009-12-06, 1388/09/15
Ethics committee reference number
5725

Health conditions studied

1

Description of health condition studied
major depressive disorder
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Severity of depression
Timepoint
Baseline and weeks 2,4 and 6
Method of measurement
Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description
Capsule Fluoxetine 40 mg/day plus Capsule Modafinil (400 mg/day) as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Cap fluoxetine 40 mg/day plus Cap. placebo as control group for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Prof. Shahin Akhondzadeh
Street address
Roozbeh Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Keshavarz Blvd
City
Tehran
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
empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty