

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

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

Hamilton 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

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work**Street address**

Roazbeh Hospital-South Kargar street

City

Tehran

Postal code**Phone**

+98 21 5541 2222

Fax**Email**

s.akhond@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work**Street address**

Roazbeh Hospital

City

Tehran

Postal code**Phone**

+98 21555412222

Fax**Email**

S.akhond@sina.tums.ac.ir

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