Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Riluzole as adjuvant therapy in the treatment o moderate to severe major depression: A double - blind placebo-controlled trial

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of Riluzole as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 40 adult inpatient 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 19 will be allocated into two groups. 20 patients will receive Citalopram 40 mg/day plus Riluzole 100mg/day (50 mg bid)and 20 participants will receive Citalopram 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307181556N54**
Registration date: **2013-07-18, 1392/04/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-07-18, 1392/04/27

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

Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Riluzole as adjuvant therapy in the treatment o moderate to severe major depression: A double - blind placebo-controlled trial

Public title

Riluzole in the treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1. Presence of Major Depressive Disorder based on DSM-IV criteria; Baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 19. Exclusion criteria: 1. Presence of Psychosis;2.any other diagnosis in Axis I and II; 3.Receiving psychotropic medications;4.receiving any antidepressants during past one month or ECT during past two months;5. Presence of hypothyroidism;6. cardiovascular problems; 7. pregnancy or nursing women; 8.7-rising liver transaminases to three times the upper limit of normal or higher

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
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshvarz Blvd
City
Tehran
Postal code
Approval date
2013-07-13, 1392/04/22
Ethics committee reference number
22192

Health conditions studied

1

Description of health condition studied
Major Depressive episode
ICD-10 code
F32
ICD-10 code description
Major 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
Tablet Citalopram 40 mg/day plus Tablet Riluzole 50 mg twice per day as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Tablet Citalopram 40 mg/day plus Tablet 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
Dr. Shahin Akhondzadeh
Street address
South Kargar Sreeet, Roozbeh Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Akbar Fotouhi
Street address
Keshvarz 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

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

South Kargar street; Roozbeh Hospital

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

S.akhond@sina.tums.ac.ir

Web page address

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

South Kargar Street; Roozbeh Hospital,

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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

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Fax

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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