Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Citichholine as adjuvant therapy in major depression: a randomized and double blind study

Protocol summary

Summary

Our study objective is to evaluate the effect of citicoline as a supplementary drug in treatment of patients suffering from depression in the range of medium to sever, who receive citalopram as the main drug, in a double blind controlled clinical trial. Fifty patients diagnosed as depressed, with a score of above 18 on Hamilton Rating Scale for Depression (HRSD), are going to be selected and randomly assigned to two groups. First group of patients receive citalopram & citicoline every 12 hours for six weeks. This is called treatment group. Second group of patients receive citalopram and placebo-100 mg every 12 hours for six weeks. This is called controlled group. Assessments are taken by psychiatrists on 2nd, 4th and 6th weeks after onset of receiving medication. Intensity changes of depression will be assessed with the help of HRSD score and will be carried out by psychiatrists

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502191556N74**
Registration date: **2015-08-29, 1394/06/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-29, 1394/06/07

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

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Citichholine as adjuvant therapy in major depression: a randomized and double blind study

Public title

The effect of Citicoline in major depression

Purpose

Treatment

Inclusion/Exclusion criteria

aInclusion criteria: age between 18 – 50 years old; diagnoses are done on the basis of Diagnostic & Statistical Mental Disorders (DSMD); HRSD score above14; signing informed consent. Exclusion criteria: demise of a close relative; having other psychocognitive affliction; taking antidepressive & psychoactive drugs within the last two months; heart complication; thyroid complication; history of ECT (Electroconvulsive Therapy); alcohol & drug addiction; reaching menopause age; pregnancy and lactation.

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: **50**
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
Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2014-07-26, 1393/05/04
Ethics committee reference number
24687

Health conditions studied

1

Description of health condition studied
Major depression
ICD-10 code
F32
ICD-10 code description
Major Depressive episode

Primary outcomes

1

Description
Severity of depression
Timepoint
Assessment in first and on 2th, 4th and 6th weeks after onset of receiving medication
Method of measurement
Measurment by HAMD

Secondary outcomes

empty

Intervention groups

1

Description
Citalopram 40 mg /day plus capsule citicolin 100 mg BID as the main drug for six weeks as the intervention group
Category
Treatment - Drugs

2

Description
Citalopram 40 mg/day plus Placebo for six weeks as the control group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharloo hospital
Full name of responsible person
Dr. Samrand Salimi
Street address
Baharloo hospital, Rahahan squre
City
Tehran

2

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Dr. Aliakbar Nejatisafa
Street address
Rouzbeh hospital, South Kargar street
City
Tehran

3

Recruitment center
Name of recruitment center
Immam Khomeini hospital
Full name of responsible person
Dr. Mohammad Arbabi
Street address
Immam Khomeini hospital, Dr. Gharib street,

Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Medical Sciences University

Full name of responsible person

Dr. Massod Yunesian

Street address

Tehran University of Medical Sciences, Ghods Avn., Keshavarz Blvd.,Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran Medical Sciences University

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

Dr. Shahin Akhondzadeh

Position

Professor of Medical Psychopharmacology

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty