

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

L-carnosine as an adjuvant in treatment of major depressive disorder : a randomized double-blind study

Protocol summary

Study aim

Comparison of efficacy of Citalopram plus L-carnosin and Citalopram plus placebo in Major Depressive Disorder

Design

Two arm parallel group randomized trial with blinded outcome and side effects assessment

Settings and conduct

Subjects will be included in psychiatric clinics of Iran Psychiatry Hospital, Tehran Psychiatry Institute and Farshchian Hospital(Hamadan).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who meet DSM-IV-TR criterion for MDD .They should be 18-60 years old and they achieve more than 18 for Hamilton Depression Scale (HamD) and sign consent form. Exclusion criteria: Substance abuse except Nicotine for 1 year before entrance, treated by any anti-depressant medication for 1 month ago, treated by ECT for 2 months ago, presence of psychotic feature, previous diagnosed as Bipolar patient, suicidal thoughts. In addition, they will evaluate for thyroid, cardiac, liver, kidney diseases, or any medical cause for depression, pregnancy, lactation before entrance and any mentioned conditions will cause exclusion from study

Intervention groups

Patients will be randomized divided into 2 groups: First group will be treated with Citalopram tablet (max. 20mg/day) plus L-carnosine tablet (400mg twice per day) for 6 weeks and another group will be treated with Citalopram tablet (max. 20mg/day) plus placebo for 6 weeks.

Main outcome variables

Severity of Major Depressive Disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170123032145N2**

Registration date: **2018-04-13, 1397/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

Registration date

2018-04-13, 1397/01/24

Registrant information

Name

Mohammadreza Shalbafan

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1665

Email address

shalbafan.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-carnosine as an adjuvant in treatment of major depressive disorder : a randomized double-blind study

Public title

L-carnosine in treatment of major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who meet DSM-IV-TR criterion for MDD They should be 18-60 years old and They achieve more than 18 for Hamilton Depression Scale (HamD) Sign consent form

Exclusion criteria:

Substance abuse except Nicotine for 1 year before entrance Treated by any anti-depressant medication for 1 month ago Treated by ECT for 2 months ago Presence of psychotic feature Previous diagnosed as Bipolar patient Suicidal thoughts They will evaluate for thyroid, cardiac, liver, kidney diseases, or any medical cause for depression, pregnancy, lactation before entrance and any mentioned conditions will cause exclusion from study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Investigators who include subjects or evaluate response or side effects are not aware that which group 1/2 is case/control.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Exp. way, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-01-05, 1396/10/15

Ethics committee reference number

IR.IUMS.FMD.REC 1396.۹۴۱۱۲۸۶۰۰۱

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Hamilton Depression Scale score

Timepoint

0, 2, 4, 6 weeks

Method of measurement

Hamilton Depression Scale

Secondary outcomes

1

Description

side effects

Timepoint

1,2,4,6 weeks

Method of measurement

side effects checklist

Intervention groups

1

Description

Intervention group: Citalopram tab (max. dose 20mg/day) plus L-carnosine tab 400 mg/ twice per day) for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Citalopram tab (max. dose 20mg/day)

plus Placebo tab/ twice per day) for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Psychiatry Hospital
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Tehran-Karaj 7 km, Tehran
City
Tehran
Province
Tehran
Postal code
۱۳۹۸۹۱۳۱۵۱
Phone
+98 21 4450 3395
Email
shalbafan.mr@iums.ac.ir

2

Recruitment center

Name of recruitment center
Tehran Psychiatry Institute
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Mansoori St., Niayesh St., Sattarkhan St., Tehran
City
Tehran
Province
Tehran
Postal code
۱۳۴۵۶۱۳۱۱۱
Phone
+98 21 6655 1665
Fax
+98 21 6655 1665
Email
shalbafan.mr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Tehran-Karaj 7 km, Tehran
City
Tehran
Province

Tehran
Postal code
۱۳۹۸۹۱۳۱۵۱
Phone
+98 21 4452 5615
Fax
+98 21 6655 1665
Email
shalbafan.mr@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Researchers
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Shalbafan
Position
Psychiatrist/ Assistant Prof.
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Iran Psychiatry Hospital, Tehran-Karaj Exp. way 7th Km, Tehran
City
Tehran
Province
Tehran
Postal code
۱۳۹۸۹۱۳۱۵۱
Phone
+98 21 4452 5615
Email
shalbafan.mr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Dr Mohammadreza Shalbafan
Position
 Psychiatrist/ Assistant Prof.
Latest degree
 Specialist
Other areas of specialty/work
 Psychiatrics
Street address
 Iran Psychiatry Hospital, Tehran-Karaj Exp. way 7th
 Km, Tehran
City
 Tehran
Province
 Tehran
Postal code
 ۱۳۹۸۹۱۳۱۵۱
Phone
 +98 21 4452 5615
Fax
 +98 21 6655 1665
Email
 shalbafan.mr@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
 Iran University of Medical Sciences
Full name of responsible person
 Dr Mohammadreza Shalbafan
Position
 Psychiatrist/ Assistant Prof.
Latest degree
 Specialist
Other areas of specialty/work
 Psychiatrics
Street address
 Iran Psychiatry Hospital, Tehran-Karaj Exp. way 7th
 Km, Tehran
City
 Tehran

Province
 Tehran
Postal code
 ۱۳۹۸۹۱۳۱۵۱
Phone
 +98 21 4452 5615
Fax
 +98 21 6655 1665
Email
 shalbafan.mr@iums.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data about main outcome of study will be published

When the data will become available and for how long

2020

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For scientific goals

From where data/document is obtainable

shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

What processes are involved for a request to access data/document

Sending an E-mail and reason for request

Comments