

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of curcumin on cognitive function and inflammatory index in people affected by major depression

Protocol summary

Study aim

curcumin effect on cognitive and inflammatory indices in patients with major depressive disorder

Design

Double blind randomized clinical trial, with two parallel arms each consists of 60 patients, simple randomized

Settings and conduct

all self referral clients of hoshiar psychology clinics of Tehran city received clinical diagnosis of major depression and were interested, screened according to criterion of study. they located in homogenized gender groups in case or control arm by simple randomization

Participants/Inclusion and exclusion criteria

age between 18 to 55 diagnosis of major depressive disorder according to DSM5 criteria able to read, write and speak eloquent in Persian no history of substance abuse and cigarette smoking no history of regular use of NSAIDs and celecoxib no history of psychotropic medications during last three years no history of herbal, nutritional or medical supplement during last three years BMI less than 35 no history of CNS affecting conditions (seizure, head trauma, multiple sclerosis) no history of other psychiatric disorders no history of any systemic condition no history of ECT therapy no history of infection during last month no suicidal idea no hormonal disturbances no need for hospitalization

Intervention groups

both case and control groups receiving 50 mg of sertraline. in addition 1g curcumin administrated in case group, control group received placebo.

Main outcome variables

cognitive function as speed processing, working memory and set shifting inflammatory indices of IL1beta, IL-6, hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200607047672N1**

Registration date: **2020-12-27, 1399/10/07**

Registration timing: **retrospective**

Last update: **2020-12-27, 1399/10/07**

Update count: **0**

Registration date

2020-12-27, 1399/10/07

Registrant information

Name

Zeynab Ali madadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8602 7558

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sa.azamy@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2020-03-04, 1398/12/14

Actual recruitment start date

2018-08-09, 1397/05/18

Actual recruitment end date

2020-03-04, 1398/12/14

Trial completion date

2020-06-03, 1399/03/14

Scientific title

Effect of curcumin on cognitive function and inflammatory index in people affected by major depression

Public title

Effect of curcumin in depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

diagnosis of major depression by psychiatrist no history of drug abuse no history of endocrinological disorders no history of immune dysfunction disorders no history of other CNS disorders not obese not being on any type of dieting no suicidal idea no psychosis not using antidepressant medications for last three months not using anti inflammatory medications not using unprescribed medicine speaking Persian fluently ability to write Persian not pregnant

Exclusion criteria:

history of drug abuse endocrinological disorders immune dysfunction disorders other CNS disorders obesity using a special form of diet suicide idea psychosis using antidepressant medications for last three months using anti inflammatory medications using unprescribed medicine pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the patients with MDD referred to medical centers, 120 people were selected by criterion sampling method based on inclusion and exclusion criteria and were randomly assigned to two groups A and B based on a table of random numbers. Then A and B groups were assigned to be curcumin and active control groups randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigators, paraclinical colleagues of the project, data analysts did not know which group A or B was the test or control. Both groups were treated with sertraline. In the control group, placebo was used, which was completely similar in color, weight and size to the curcumin capsule.

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

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n13, hamid Ave, Shariatii St, north to motahari St

City

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Province

Tehran

Postal code

1639666355

Approval date

2017-05-04, 1396/02/14

Ethics committee reference number

IR.IUMS.REC.1397.1167

Health conditions studied**1****Description of health condition studied**

Major Depression

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

Primary outcomes**1****Description**

speed processing time in trail making task A

Timepoint

At beginning, after 6 weeks and 12 weeks

Method of measurement

trail making task A

2**Description**

speed processing time in trail making task B

Timepoint

At beginning, after 6 weeks and 12 weeks

Method of measurement

trail making task B

3**Description**

executive function score on verbal fluency task

Timepoint

At beginning, after 6 weeks and 12 weeks

Method of measurement

verbal fluency task

4

Description

executive function score on Wisconsin sorting test

Timepoint

At beginning, after 6 weeks and 12 weeks

Method of measurement

Wisconsin sorting test

5

Description

serum level of interleukin 1 beta

Timepoint

At the beginning and week 12

Method of measurement

Serum test, Enzyme linked Immuno Assay ,ELISA

6

Description

serum level of interleukin 6

Timepoint

At the beginning and week 12

Method of measurement

Serum test, Enzyme linked Immuno Assay ,ELISA

7

Description

serum level of high sensitivity C reactive protein

Timepoint

At the beginning and week 12

Method of measurement

Serum test, Enzyme linked Immuno Assay ,ELISA

8

Description

executive function score on Tower of London Test

Timepoint

At beginning, after 6 weeks and 12 weeks

Method of measurement

Tower of London Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sertraline 50 mg and curcumin 1000 mg so that in the first four days of sertraline 25 mg, then 50 mg sertraline until the end of the intervention. Curcumin at a dose of 1000 mg daily was added to the

standard treatment in divided doses of 500 mg in the morning and at noon with water.

Category

Treatment - Drugs

2

Description

Control group: sertraline 50 mg and placebo. In the first four days, sertraline received 25 mg, then 50 mg sertraline until the end of the intervention. Placebo (roasted rice powder) at a dose of 1000 mg per day, divided into It was added to the standard treatment in two doses of 500 mg in the morning and at noon with water.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

hoshiar psychological clinic

Full name of responsible person

Saeed Azami

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n2 Bahar building masud ave ,north sheykhbahai

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shima Jazayeri

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Iran University of medical science, hemmat Expressway

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Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
20

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Zeynab Ali madadi

Position
psychiatrist

Latest degree
Specialist

Other areas of specialty/work
nutrition and psychiatry

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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
All data is potentially shareable after individuals become unidentifiable

When the data will become available and for how long
available after 6 months of publication

To whom data/document is available
Researchers working in academic and scientific

institutions

Under which criteria data/document could be used

Academic and scientific research cases

From where data/document is obtainable

Dr Zeynab Ali madadi zeinabalimadadi@gmail.com or
hoshiar psychological center Dr Aaeed Azami
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What processes are involved for a request to access data/document

Send email to the responsible author. Authentication documents certified by the applicant or the relevant research center must be sent. Specify how and with what intention the information will be used. according to this instruction, data access, treatment protocol, data analysis map and clinical study report will be available within two working weeks.

Comments