

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of therapeutic effects of Nigella sativa extract on serum Brain-Derived Neurotrophic Factor (BDNF) and depression and anxiety score in patients with depression

Protocol summary

Study aim

Evaluation of therapeutic effects of Nigella sativa extract on serum Brain-Derived Neurotrophic Factor (BDNF) and depression and anxiety score in patients with depression referred to Artesh 505 hospital

Design

Clinical trial with control group with parallel groups, phase 2-3 on 50 patients

Settings and conduct

This study will be performed in 505 Artesh Hospital in Tehran and patients with depression will be treated with Nigella sativa capsules. Before and 6 weeks after treatment, the severity of depression as well as the level of serum BDNF in them will be measured and compared with the beginning of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 65 years, having Major Depression, referring to the 505 Artesh Hospital, treated only with sertraline, moderate to severe depression, having the written informed consent to participate in the study Exclusion criteria: failure to take medication regularly, drug intolerance, allergy to Nigella sativa, having systemic diseases, pregnancy or breastfeeding in women, tendency to leave during the study

Intervention groups

Intervention group: Patients in this group will be evaluated for depression severity and serum BDNF after entering the study. Patients will be then treated with capsules containing 1000 mg of Nigella sativa extract daily along with sertraline. After 6 weeks, the patients' depression level as well as the level of serum BDNF in them will be measured again. Control group: Patients in this group will be evaluated for depression severity and serum BDNF after entering the study. Patients will be then receiving placebo capsules, daily, containing starch along with sertraline. After 6 weeks, the patients'

depression level as well as the level of serum BDNF in them will be measured again.

Main outcome variables

Severity of depression and the level of serum BDNF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N17**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-09, 1400/05/18

Expected recruitment end date

2021-09-09, 1400/06/18

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of therapeutic effects of Nigella sativa extract on serum Brain-Derived Neurotrophic Factor (BDNF) and depression and anxiety score in patients with depression

Public title
Nigella sativa extract and depression

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years Having Major Depression Referring to the 505 Artesh Hospital Treated only with sertraline Moderate to severe depression Having the written informed consent to participate in the study

Exclusion criteria:

Failure to take medication regularly Drug intolerance Allergy to Nigella sativa Having systemic diseases Pregnancy or breastfeeding in women Tendency to leave during the study

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not 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 the Arteshof the of the Islamic Republic of Iran University of Medical Sciences

Street address

Artesh University of Medical Sciences, Etemadzadeh

St., West Fatemi St., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.AJAUMS.REC.1399.220

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F33.0

ICD-10 code description

Major depressive disorder, recurrent, mild

Primary outcomes

1

Description

Severity of depression

Timepoint

At the beginning of the intervention and 6 weeks after treatment

Method of measurement

Using Depression, Anxiety and Stress Scale - 21 (DASS-21)

2

Description

Serum levels of Brain-Derived Neurotrophic Factor (BDNF)

Timepoint

At the beginning of the intervention and 6 weeks after treatment

Method of measurement

By enzyme-linked immunosorbent assay (ELISA) kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will be evaluated for depression severity through Depression, Anxiety and Stress Scale - 21 (DASS-21) questionnaire and serum BDNF through ELISA kits after entering the study. Patients will be then treated with capsules containing 1000 mg of Nigella sativa extract daily along

with sertraline. After 6 weeks, the patients' depression level as well as the level of serum BDNF in them will be measured again.

Category

Treatment - Drugs

2**Description**

Control group: Patients in this group will be evaluated for depression severity through Depression, Anxiety and Stress Scale - 21 (DASS-21) questionnaire and serum BDNF through ELISA kits after entering the study.

Patients will be then receiving placebo capsules, daily, containing starch along with sertraline. After 6 weeks, the patients' depression level as well as the level of serum BDNF in them will be measured again.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

505 Arthesh hospital

Full name of responsible person

Vahid Donyavi

Street address

505 Arthesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1956944141

Phone

+98 21 2248 1806

Email

donyavi_vahid@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zeshk

Street address

Artesh University of Medical Sciences, Etemadzadeh St., West Fatemi St., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8833 7920

Email

Yousefi.Zeshk@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh University of Medical Sciences

Proportion provided by this source

100

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**

Artesh University of Medical Sciences

Full name of responsible person

Vahid Donyavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

505 Arthesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1956944141

Phone

+98 21 2248 1806

Email

donyavi_vahid@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Vahid Donyavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

505 Artesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1956944141

Phone

+98 21 2248 1806

Email

donyavi_vahid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Vahid Donyavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

505 Artesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1956944141

Phone

+98 21 2248 1806

Email

donyavi_vahid@yahoo.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Artesh University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments