

# 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

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

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**Email**

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**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**

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**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**

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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**

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**