

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Evaluation the effect of Nigella Sativa oil on Acute Ischemic Stroke Outcome: A triple blind randomized placebo controlled trial

#### Protocol summary

Registration timing: **prospective**

#### Study aim

The aim of this clinical trial is to assess efficacy of Nigella Sativa oil on ischemic stroke patient's functional outcome (at least 50% improvement in the 3-month NIHSS compared to the baseline score ) compared with placebo.

Last update: **2019-01-14, 1397/10/24**

Update count: **1**

#### Registration date

2019-01-05, 1397/10/15

#### Design

A randomized controlled clinical trial and triple blind, parallel study

#### Registrant information

##### Name

Hossein Yusefi

##### Name of organization / entity

Qom University of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3886 0146

##### Email address

driran1399@gmail.com

#### Settings and conduct

This study is conducted at Shahid Beheshti Hospital in Qom and is blinded by placebo

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Acute ischemic stroke hospitalization in Shahid beheshti hospital; 2-Not having a severe disability after stroke(NIHSS<20); . Exclusion criteria: 1- Request of patients to Exit from the study; 2- Previous chronic disease interferes with the performance evaluation in patients such as: chronic infections, liver or kidney failure, cancers; 3- Residual weakness of previous stroke; 4- Pregnancy or breastfeeding or any conditions that makes follow up impossible; 5- Sever loss of Consciousness; 6- Thrombolytic therapy; 7- Endarterectomy

#### Expected recruitment start date

2019-02-20, 1397/12/01

#### Expected recruitment end date

2019-08-23, 1398/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

patient with patient with acute ischemic stroke which is divided into two groups of Nigella Sativa oil capsule and placebo capsule .placebo similar to the drug.

#### Scientific title

Evaluation the effect of Nigella Sativa oil on Acute Ischemic Stroke Outcome: A triple blind randomized placebo controlled trial

#### Main outcome variables

Disability of patients

#### Public title

Effect of Nigella sativa oil on Prognosis of Acute Ischemic

#### General information

##### Reason for update

##### Acronym

AEH

##### IRCT registration information

IRCT registration number: **IRCT20170112031893N4**

Registration date: **2019-01-05, 1397/10/15**

Stroke Patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Acute ischemic stroke hospitalization in Shahid Beheshti hospital Not having a severe disability after stroke(NIHSS<20) Not to receive antioxidants (such as vitamin C and E) constantly Not affected by AIDS and neurodegenerative diseases (e.g. Alzheimer's, Parkinson's, amyotrophic lateral sclerosis)

**Exclusion criteria:**  
Request of patients to Exit from the study; Previous chronic disease interferes with the performance evaluation in patients such as: chronic infections, liver or kidney failure, cancers; Residual weakness of previous stroke Pregnancy or breastfeeding or any conditions that makes follow up impossible Sever loss of Consciousness Thrombolytic therapy Endarterectomy

**Age**  
From **40 years** old to **100 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients were randomly allocated into two groups using random numbers table developed by Random Allocation Software

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

### **Street address**

Vice chancellor for research of Qom University of Medical Sciences, Safashar road, Qom, Iran

### **City**

Qom

### **Province**

Ghous

### **Postal code**

87366-37169

### **Approval date**

2018-12-04, 1397/09/13

### **Ethics committee reference number**

IR.MUQ.REC.1397.135

## Health conditions studied

### 1

#### **Description of health condition studied**

Acute ischemic stroke

#### **ICD-10 code**

I63

#### **ICD-10 code description**

Cerebral infarction

## Primary outcomes

### 1

#### **Description**

Prognosis after stroke

#### **Timepoint**

At hospitalization(0), discharge(1), and after 3 months(2)

#### **Method of measurement**

Functional status score based on NIHSS (National institutes of health stroke scale)(at least 50% reduction in NIHSS score in 3-month compared to the baseline score

## Secondary outcomes

### 1

#### **Description**

Prognosis after stroke

#### **Timepoint**

At hospitalization(0), discharge(1), and after 3 months(2)

#### **Method of measurement**

Modified Rankin scale (MRS)

## Intervention groups

### 1

#### **Description**

Intervention group:The group used Nigella Sativa oil capsules amount 3 gram for 3 months, every day

#### **Category**

Treatment - Drugs

## 2

### Description

Control group: The group used placebo capsules amount 3 gram for 3 months, every day

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti hospital

##### Full name of responsible person

Ehsan Sharifipour

##### Street address

Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

##### City

Qom

##### Province

Ghous

##### Postal code

3713649373

##### Phone

+98 25 3886 0146

##### Email

Ehsansharifipour@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghous University of Medical Sciences

##### Full name of responsible person

Hossein Saghafi

##### Street address

Namber 83, Alley 4, Alley 1.1, Safashahr Street

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

driran1399@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ghous 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

Ghous University of Medical Sciences

##### Full name of responsible person

Ehsan Sharifi Pour

##### Position

Professor assistant

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurology

##### Street address

Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ghous University of Medical Sciences

##### Full name of responsible person

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##### Position

Professor assistant

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurology

##### Street address

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##### City

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##### Province

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**Person responsible for updating data****Contact****Name of organization / entity**

Ghoush University of Medical Sciences

**Full name of responsible person**

Muhammad Hossein Yusefi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Neuroscience

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**Province**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

With attention due to the type of study and publication of the article, there was no need to mention this

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

With attention due to the type of study and publication of the article, there was no need to mention this

**When the data will become available and for how long**

With attention due to the type of study and publication of the article, there was no need to mention this

**To whom data/document is available**

With attention due to the type of study and publication of the article, there was no need to mention this

**Under which criteria data/document could be used**

With attention due to the type of study and publication of the article, there was no need to mention this

**From where data/document is obtainable**

With attention due to the type of study and publication of the article, there was no need to mention this

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

With attention due to the type of study and publication of the article, there was no need to mention this

**Comments**

With attention due to the type of study and publication of the article, there was no need to mention this