

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

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Hossein Saghafi

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Neurology

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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

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Other areas of specialty/work

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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