

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of combined extract of Nigella Sativa and Thymus Vulgaris on refractory seizures in children

Protocol summary

Summary

this study is a randomised double blind,patients and researcher, crossover clinical trial.the objective of study is assessment of Efficacy of combined extract of Nigella Sativa and Thymus Vulgaris on refractory seizures in children in Ahvaz city.The patients will be divided randomly into two groups.15 Patients in the intervention group receive NS and TV extract as an adjunctive therapy. 15 patients in the control group receive placebo with same shape.Then all the patients will be evaluated for two weeks (as washout period) after two months in the terms of duration and the frequency of epilepsy and side effects. Then after crossover the prepared extracts and placebo will be administered for groups for another two months . Then the frequency and duration of seizure will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052428043N1**

Registration date: **2016-12-09, 1395/09/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Maryam Heydarzad Zadeh

Name of organization / entity

Ahvaz Judishapur University Of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-03-10, 1395/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of combined extract of Nigella Sativa and Thymus Vulgaris on refractory seizures in children

Public title

Efficacy of combined extract of Nigella Sativa and Thymus Vulgaris on refractory seizures in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : children with a diagnosis of refractory seizures; having at least two episodes of seizures during one month prior to study entry; regular consumption of previous antiepileptic drugs. Exclusion criteria ; occurrence of adverse side effects such as nausea and vomiting; increase the number and duration of seizure after starting NS and TV; and dissatisfaction to continue participation in study.

Age

From **3 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz ,Golestan Blv, Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

Approval date

2015-06-06, 1394/03/16

Ethics committee reference number

IR.AJUMS.REC.1394.141

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40,G41

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

seizures frequency per week

Timepoint

two months prior to study-five months during study

Method of measurement

visitable seizure scaling

2

Description

seizure duration

Timepoint

two months prior to study-five months during study

Method of measurement

visitable seizure scaling

Secondary outcomes

1

Description

side effects

Timepoint

five months

Method of measurement

visitable scaling

Intervention groups

1

Description

intervention group: patients with age 3-12 years receive 5cc of prepared extract(115 mg of extract is found in 5 cc of prepared drug) three times a day and patients with age >12 years receive 7.5 cc of prepared extract three times a day for two months. Then all the patients will be evaluated for two weeks (as washout period) after two months in the terms of duration and the frequency of epilepsy and side effects. Then the prepared placebo will be administered for another two months.

Category

Treatment - Drugs

2

Description

control group: patients with age 3-12 years receive 5cc of prepared placebo three times a day and patients with age >12 years receive 7.5 cc of prepared placebo three times a day for two months. Then all the patients will be evaluated for two weeks (as washout period) after two months in the terms of duration and the frequency of epilepsy and side effects. Then the prepared extracts extract(115 mg of extract is found in 5 cc of prepared drug)with the same dosage as adjunctive therapy will be administered for another two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital
Full name of responsible person
Maryam Heydarazad Zadeh
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of Ahvaz Jundishapur University of
Medical Sciences
Full name of responsible person
Mostafa Fegghi
Street address
Golestan BLV , Ahvaz
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Ahvaz
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes

Title of funding source
Vice chancellor of Ahvaz Jundishapur University of
Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty