Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 childrenin 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 administrated 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 Heydarazad 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 Univercity of Medical Sciences
Street address
Ahvaz ,Golestan Blv, Ahvaz Jundishapur Univercity 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 effets
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 administrated foranother two months.
Category
Treatment - Drugs

2

Description
contorol 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 plasebo 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 administrated 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

Street address

Pediatrics Yard,Golestan Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mostafa Feghhi

Street address

Golestan BLV , Ahvaz

City

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Maryam Heydar Azadzaeh

Position

Pediatrics Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Associate Professor, Department of Pediatric Neurology

Other areas of specialty/work

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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