Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of Nigella Sativa oil in the treatment of Nasal allergic inflammation

Protocol summary

Summary

This randomized, double blind, placebo controlled trial, was conducted to asses the efficacy of Black seed on the treatment of allergic rhinitis. Totally, 66 males and females aged 15–65 years who affected by allergic rhinitis and with no history of medication during last 4 weeks are recruited. The patients are randomly divided to two groups of placebo and intervention. The intervention group receive 40-80 mg/kg/day to maximum 3 gr of Black seed caps prepared from the extract. We measure IgE and Eosinophil count of serum and nasal secretion before and after the intervention. The scoring will be engaged based on severity of symptoms before and after the exposure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806212446N1**
Registration date: **2010-01-09, 1388/10/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-01-09, 1388/10/19

Registrant information

Name

Soheila Nikakhlagh

Name of organization / entity

Ahwaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1336 2411

Email address

bioinfo2003@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Ahwaz JondiShapour University of Meical Sciences

Expected recruitment start date

2007-01-14, 1385/10/24

Expected recruitment end date

2009-01-14, 1387/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Nigella Sativa oil in the treatment of Nasal allergic inflammation

Public title

Evaluation of the efficacy of Black seed oil in the treatment of Nasal allergic inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 15–65 years with allergic rhinitis and no consumption of steroids and antihistamines and decongestants during 4 weeks before the study Exclusion criteria: Patients who use steroids or antihistamines and decongestants during the study

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **66**

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
Ahwaz Jondishapour University of Medical Sciences

Street address
Research Deputy, Ahwaz Jondishapour University of Medical Sciences

City
Ahwaz

Postal code
15794

Approval date
2008-04-20, 1387/02/01

Ethics committee reference number
د/پ/102

Health conditions studied

1

Description of health condition studied
Allergic rhinitis

ICD-10 code
J30.4

ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
IgE of serum and nasal secretion

Timepoint
at first and one month later

Method of measurement
Laboratory

Secondary outcomes

1

Description
Eosinophil count of serum and nasal secretion

Timepoint
at first and one month later

Method of measurement
Laboratory

Intervention groups

1

Description
Interventio: 40-80 mg/kg/day to maximum 3 gr of Black seed

Category
Treatment - Drugs

2

Description
Control: Placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person

Street address

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy, Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person
Dr. Mostafa Feghhi

Street address
Research Deputy, Ahwaz Jondishapour University of Medical Sciences

City
Ahwaz

Grant name

Grant code / Reference number

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

Title of funding source

Research Deputy, Ahwaz Jondishapour 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
Ahwaz Jondishapour University of Medical Sciences

Full name of responsible person
Soheila Nikakhlagh

Position
Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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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