

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

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

Protocol summary

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Summary

This randomized, double blind, placebo controlled trial, was conducted to assess 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.

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

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

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

102/پ/د

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 Fegghi

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

Contact

Name of organization / entity

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Full name of responsible person

Soheila Nikakhlagh

Position

Superspecialty in E.N.T

Other areas of specialty/work

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Person responsible for updating data

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

Street address

Imam Khomeini Hospital

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Phone

Fax

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Web page address

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