

# 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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**Position**

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**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

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**City**

Ahwaz

**Postal code**

**Phone**

**Fax**

**Email**

**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*