

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of *Nigella sativa* nasal spray on the treatment of Chronic rhino sinusitis.

Protocol summary

Summary

In this double-blind, clinical trial, the aim of this study is evaluation of *Nigella sativa* nasal spray effects on chronic rhinosinusitis. Inclusion criteria: patients with chronic rhinosinusitis who have indication for drugs intervention, age between 18 and 72 years. Exclusion criteria: People who have allergies to herbs; People who do not follow up; People who do not have the consent to participate in the study. The sample size in this study is 72, patients will be allocate randomly in two parallel groups. The intervention group are treated with 2 puffs of nasal spray/ daily, and the placebo group are treated with 2 puffs of sodium chloride nasal spray daily, the length course of treatment is 8 weeks in both groups. After treatment duration, the recovery rate of patients in the two groups is assessed using a pre-prepared questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082712782N17**

Registration date: **2017-09-23, 1396/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-23, 1396/07/01

Registrant information

Name

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice President of Research, School of Medicine, Isfahan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of *Nigella sativa* nasal spray on the treatment of Chronic rhino sinusitis.

Public title

Effect of *Nigella sativa* Nasal Spray on the Treatment of Patients with Chronic Nasal Sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with chronic rhinosinusitis who have indication for drugs intervention, age between 18 and 72 years. Exclusion criteria: People who have allergies to herbs; People who do not follow up; People who do not have the consent to participate in the study.

Age

From **18 years** old to **72 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

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7346181746

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.MUI.REC.1396.30324

Health conditions studied**1****Description of health condition studied**

Chronic Rhinosinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes**1****Description**

Recovery

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Prepared questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: under Treatment with 2 puffs Nigella sativa Nasal spray / daily

Category

Treatment - Drugs

2**Description**

Control group: under treatment with 2 puffs sodium chloride nasal spray /daily

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin Hospital

Full name of responsible person

Ahmad Rezaeian

Street address

Amin Hospital, Isfahan, Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mansour Siavash

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Isfahan University of medical sciences, hezar jareeb, Isfahan, Iran.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Isfahan 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

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Person responsible for general inquiries

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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