Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Nasil drop (sesame based black seeds) versus placebo on treatment of chronic rhinosinusitis: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Nasil drop (sesame based black seeds) versus placebo on treatment of chronic rhinosinusitis. Design: a triple blind randomized clinical trial. Setting and conduct: The eligible patients with chronic rhinosinusitis who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 64 years; chronic rhinosinusitis. Exclusion criteria: Pregnancy; fever; immunosuppression; nasal polyp; sensitivity to black seeds or sesame. Intervention group: Nasil drop (sesame based black seeds) one drop in the right nostril at the first night, one drop in the left nostril at the second night, two drops in the right nostril at the third night, two drops in the left nostril at the fourth night; three drops in the right nostril at the fifth night and three drops in the left nostril at the sixth night; then, the drop will be quit for one week and again drop will be started the same way once more. Control group: Placebo drop (including distilled water) one drop in the right nostril at the first night, one drop in the left nostril at the second night, two drops in the right nostril at the third night, two drops in the left nostril at the fourth night; three drops in the right nostril at the fifth night and three drops in the left nostril at the sixth night; then, the drop will be quit for one week and again drop will be started the same way once more. Primary outcome: (a) status of rhinosinusitis based on Vas score before intervention, immediately after intervention and 3 weeks later; (b) status of rhinosinusitis based on Snot-22 score before intervention, immediately after intervention and 3 weeks later; (c) status of rhinosinusitis based on endoscopic before intervention, immediately after intervention and 3 weeks later. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703079014N149**
Registration date: **2017-03-12, 1395/12/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nasil drop (sesame based black seeds) versus placebo on treatment of chronic rhinosinusitis: a triple blind randomized clinical trial

Public title

Effect of Nasil drop (sesame based black seeds) versus placebo on treatment of chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 64 years; chronic rhinosinusitis. Exclusion criteria: Pregnancy; fever; immunosuppression; nasal polyp; sensitivity to black seeds or sesame.

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

IR.UMSHA.REC.1395.3

Health conditions studied

1

Description of health condition studied

chronic rhinosinusitis

ICD-10 code

J32.9

ICD-10 code description

Chronic sinusitis, unspecified

Primary outcomes

1

Description

status of rhinosinusitis

Timepoint

before intervention, immediately after intervention and 3 weeks later

Method of measurement

based on Vas score

2

Description

status of rhinosinusitis

Timepoint

before intervention, immediately after intervention and 3 weeks later

Method of measurement

based on Snot-22 score

3

Description

status of rhinosinusitis

Timepoint

before intervention, immediately after intervention and 3 weeks later

Method of measurement

based on endoscopic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Nasil drop (sesame based black seeds) one drop in the right nostril at the first night, one drop in the left nostril at the second night, two drops in the right nostril at the third night, two drops in the left nostril at the fourth night; three drops in the right nostril at the fifth night and three drops in the left nostril at the sixth night; then, the drop will be quit for one week and again drop will be started the same way once more.
Category
Treatment - Drugs

2

Description
Control group: Placebo drop (including distilled water) one drop in the right nostril at the first night, one drop in the left nostril at the second night, two drops in the right nostril at the third night, two drops in the left nostril at the fourth night; three drops in the right nostril at the fifth night and three drops in the left nostril at the sixth night; then, the drop will be quit for one week and again drop will be started the same way once more.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr Tahereh Mozayyan
Street address
Besat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
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 the Technology, Hamadan 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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Department of Epidemiology

Full name of responsible person
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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