

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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

Besat Hospital

##### Full name of responsible person

Dr Tahereh Mozayyan

##### Position

Resident of ENT

##### Other areas of specialty/work

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

##### Postal code

##### Phone

+98 81 3364 0030

##### Fax

##### Email

dr\_t\_mozayyan@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Besat Hospital

##### Full name of responsible person

Dr Rooholah Abbasi

##### Position

ENT specialist

##### Other areas of specialty/work

##### Street address

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r.abbasi@umsha.ac.ir

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

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Medical Sciences, Shahid Fahmideh Ave

**City**

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6517838695

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poorolajal@umsha.ac.ir

**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*