

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The efficacy of Nigella sativa nasal oil drop on chronic rhinosinusitis patients' quality of life in comparison with placebo.

Protocol summary

Summary

This double blind randomized clinical trial with placebo will evaluate the efficacy of Nigella sativa nasal oil drop on chronic rhinosinusitis patients' quality of life. 52 Patients with eligible criteria (existence of 2 major signs or one major and 2 minor signs of rhinosinusitis in patients; patients have at least 12 consecutive weeks' duration of rhinosinusitis; patients have proved rhinosinusitis by CT-scan; patients are 16 to 65 years old) are divided in two 26 people equal groups by Balanced Block Randomization. Patients in both groups evaluate by major and minor symptoms and signs of rhinosinusitis and SNOT-22 questionnaire before and a week after intervention (day 0 and day 28). The drug group (Nigella sativa oil in sesame oil base) receives three drops in both nostrils twice a day. And the other group receives sesame oil in the same manner. Mean of SNOT-22 result score changes and Changes in Major and minor symptoms and signs of rhinosinusitis in two groups will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202088961N1**

Registration date: **2013-01-01, 1391/10/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-01, 1391/10/12

Registrant information

Name

Mohammadreza Masroorchehr

Name of organization / entity

Shahid Beheshti University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

m.masroorchehr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Nigella sativa nasal oil drop on chronic rhinosinusitis patients' quality of life in comparison with placebo.

Public title

The efficacy of Nigella sativa on chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:existence of 2 major signs or one major and 2 minor signs of rhinosinusitis in patients; patients have at least 12 consecutive weeks' duration of rhinosinusitis;patients have proved rhinosinusitis by CT-scan; patients are 16 to 65 years old exclusion criteria: pregnant patient; patients who are taking daily corticosteroid drugs; immunocompromised patients; patients having fever more than 37.8c; existence of any

polyp in the nasal cavity Drop out: patient drug intolerance; patient pregnancy when using drug; fever more than 38.5 c when using drug; patient unwillingness to continue participating in clinical trial

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

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

Shahid Beheshti University of Medical sciences

Street address

next to Ayatollah Taleghani Hospital, Evin, Shahid Chamran Expressway, Tehran

City

Tehran

Postal code

Approval date

2012-01-08, 1390/10/18

Ethics committee reference number

400/7872

Health conditions studied

1

Description of health condition studied

Chronic Rhinosinusitis

ICD-10 code

J32.9

ICD-10 code description

Sinusitis (chronic) NOS

Primary outcomes

1

Description

SNOT-22 Questionnaire result score

Timepoint

before intervention day(0), and a week after the end of intervention day(28)

Method of measurement

SNOT-22 Questionnaire

2

Description

Facial pain/pressure

Timepoint

days (0), (28)

Method of measurement

yes/ No

3

Description

Facial congestion/fullness

Timepoint

days (0), (28)

Method of measurement

yes/ no

4

Description

Nasal obstruction/blockage

Timepoint

days (0), (28)

Method of measurement

yes/ no

5

Description

Nasal discharge/purulence, discolored posterior drainage

Timepoint

days (0), (28)

Method of measurement

yes/ no

6

Description

Hyposmia/anosmia

Timepoint

days (0), (28)

Method of measurement

yes/ no

7

Description

Purulence on nasal examination

Timepoint

days (0), (28)

Method of measurement

yes/ no

8**Description**

Headache

Timepoint

days (0), (28)

Method of measurement

yes/ no

9**Description**

Fever (nonacute rhinosinusitis)

Timepoint

days (0), (28)

Method of measurement

yes/ no

10**Description**

Halitosis

Timepoint

days (0), (28)

Method of measurement

yes/ no

11**Description**

Fatigue

Timepoint

days (0), (28)

Method of measurement

yes/ no

12**Description**

Dental pain

Timepoint

days (0), (28)

Method of measurement

yes/ no

13**Description**

Cough

Timepoint

days (0), (28)

Method of measurement

yes/ no

14**Description**

Ear pain/pressure/fullness

Timepoint

days (0), (28)

Method of measurement

yes/ no

Secondary outcomes**1****Description**

Side effects

Timepoint

before intervention and days 1,7,14,21,28

Method of measurement

Questionnaire

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

Intervention:Nigella sativa oil in base of sesame oil

Category

Treatment - Drugs

2**Description**

Control:sesame oil

Category

Placebo

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

Firoozgar Hospital

Full name of responsible person

Mohammad reza Masroorchehr

Street addressShahid Farhang-e-Hoseini St ,after Taleghani Cross,
Vali-e-asr Ave**City**

Tehran

2**Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

Full name of responsible person

Mohammad reza Masroorchehr

Street address

Hefdah-e-Shahrivar St, Bank-e-Melli Sq

City

Rasht

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Shahid Beheshti University of Medical sciences

Full name of responsible person

Dr. Mehdi Besharat

Street addressLoghmanehakim Hospital,Kamali St,Lashkar Cross,
South karegar Ave**City**

Tehran

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical sciences, Faculty of Traditional Medicine

Full name of responsible person

Mohammad reza Masroorchehr

Position

Ph.D student of Traditional Medicine

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

Shams Alley, opposite Tavanir, Vali-e-Asr Ave

City

Tehran

Postal code**Phone**

+98 218877352125

Fax**Email**m.masroorchehr@sbmu.ac.ir,
masroor_shahr@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical sciences

Full name of responsible person

Mohammad reza Masroorchehr

Position

Ph.D student of Traditional Medicine

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

No 25,Lale St,Fifth Taleghani St,Moallem Ave

City

Rasht

Postal code**Phone**

+98 13 1222 0149

Fax**Email**m.masroorchehr@sbmu.ac.ir,
masroor_shahr@yahoo.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical sciences

Full name of responsible person

Mohammad reza Masroorchehr

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Ph.D student of Traditional Medicine

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

No 25,Lale Alley,Fifth Taleghani St,Moallem Ave

City

Rasht

Postal code**Phone**

+98 13 1222 0149

Fax**Email**m.masroorchehr@sbmu.ac.ir,
masroor_shahr@yahoo.com**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*