Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 intolerancy; 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 weak 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 address
Shahid 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 address
Loghmanehakim 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
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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