

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of an anise-based product in Iranian traditional medicine, on the Treatment of patients with chronic rhinosinusitis (CRSsNP) , in comparison to fluticasone nasal spray

Protocol summary

Summary

This Clinical Trial will evaluate the Effects of a herbal product based on Anise (Nasal Drop) on treatment of chronic Rhinosinusitis without polyps. 74 patients between 18 to 75 years old with chronic nasal complaints (over 12 weeks) referred to the ENT clinics after examination, diagnostic endoscopy and CT scan will diagnose as CRS and can enter to study. Patients eligible for inclusion in the study will divided by Block Randomization method into two groups. Treatment duration is one month in both groups. Patients in both groups evaluate by major and minor symptoms and signs of Rhinosinusitis and SNOT-22 questionnaire before and after intervention (day 0 and day 28). Intervention Group will receive herbal nasal drop two times daily 3 drop in each nostril plus nasal irrigation for one month. Control group will receive Fluticasone spray two puff in each nostril Two times daily plus nasal irrigation for one month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010516083N1**
Registration date: **2014-08-29, 1393/06/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

Shima Vazifekkhah

Name of organization / entity

TUMS

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2015-03-07, 1393/12/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an anise-based product in Iranian traditional medicine, on the Treatment of patients with chronic rhinosinusitis (CRSsNP) , in comparison to fluticasone nasal spray

Public title

The effect of an anise-based product in Iranian traditional medicine, on the Treatment of patients with chronic rhinosinusitis (CRSsNP) , in comparison to fluticasone nasal sprayMedicine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with presence of chronic rhinosinusitis symptoms for at least 12 weeks; positive

CT result indicating the opacity and swelling of the sinus; Patients 18 to 75 years of both sexes; Treatment with systemic or nasal antibiotics or corticosteroids within 4 weeks before visit; Treatment with oral corticosteroids within the 30 days before visit; Treatment with topical corticosteroids within 15 days before visit. Exclusion criteria: nasal and sinus surgery within the last 5 years; Presence of moderate to severe co-morbid asthma and mild asthma having exacerbation within 30 days prior to trial inclusion; Rhinitis medicamentosa (drug induced rhinitis); Known hypersensitivity to the medication or excipients; The signs and symptoms of bacterial sinusitis (fever ≥ 38.5 , ocular complications, severe unilateral frontal headache or toothache); Acute seasonal allergy; other diseases which in the opinion of the investigator disqualifies the patient for trial enrolment (such as heart failure, kidney, lung and liver, drug addiction or alcoholism, neurological or psychiatric diseases, cancer, immunodeficiency) in the past 5 years; any side effect during treatment; Pregnancy; Breastfeeding

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice-chancellor for research

Street address

Blv Keshavarz, Ghods St., 6th floor

City

Tehran

Postal code**Approval date**

2014-01-27, 1392/11/07

Ethics committee reference number

130/2497/92/3

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

Chronic sinusitis, unspecified

ICD-10 code

J32.9

ICD-10 code description

Sinusitis (chronic) NOS

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

recovery

Timepoint

before intervention (day 0), and end of intervention (day 28)

Method of measurement

SNOT-22 Questionnaire

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

Side effects

Timepoint

day 7; day 28

Method of measurement

Ask the patient; The patient stated

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

Intervention: herbal nasal drop two times daily 3 drop in each nostril plus nasal irrigation for one month

Category

Treatment - Drugs

2**Description**

Control: Fluticasone spray two puff in each nostril Two times daily plus nasal irrigation for one month

Category

Treatment - Drugs

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

ENT Clinic in Emam Khomeini Hospital

Full name of responsible person

Dr Babak Saedi

Street address

Kshavarz Blv

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masud Yunesian

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Keshavarz Blv. Corner of Ghods St.

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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

Deputy of Research, Tehran 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**

School of Traditional Medicine, Tehran University Of Medical Science

Full name of responsible person

Shima Vazifekkhah

Position

Md. Phd Student of TIM

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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Position

Associated Professor of Tehran University of Medical Sciences, Otolaryngologist

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School of Traditional Medicine of Tehran University of Medical Sciences

Full name of responsible person

Shima Vazifekkhah

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MD. Phd student in Traditional Iranian Medicine

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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*