Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative evaluation of the influence of Marjoram oil Extract (Origanum Vulgare) in treatment of chronic rhinosinusitis without nasal polyps with fluticasone spray and sesame oil, concomitant with Life style modification of Traditional Persian Medicine, (a randomized, double-blind, clinical trial)

Protocol summary

Study aim

Determination of the influence of Marjoram oil Extract (Origanum Vulgare) in treatment of chronic rhinosinusitis without nasal polyps compare with fluticasone spray and placebo, concomitant with Life style modification of Traditional Persian Medicine. Determination and comparison of mean scores of patients' symptoms (according to SNOT22 questionnaire) in marjoram group with fluticasone group before and after treatment. Determine and comparison the CT scan of patients (according to Lund Makey scale) in the Marjoram group with fluticasone before and after treatment. Determination and comparison of mean scores of patients' symptoms (according to SNOT22 questionnaire) in Marjoram group with placebo group before and after treatment. Determine and comparison the possible side effects of Marjoram and fluticason group. Determination of the frequency of major and minor symptoms in chronic rhinosinusitis in 3 groups after receiving the drug.

Design

In this research, 75 eligible patients referring to 5 Azar Hospital in Gorgan were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into 2 intervention and 1 control groups.

Settings and conduct

Patients who will be referred to "5 Azar Hospital in Gorgan" with diagnosis of chronic rhinosinusitis without polyp will be studied. This study is Randomized double-blind placebo-controlled clinical trial. Participants, clinical care provider, Investigator, outcome assessor, and data analyzers are also blinded in this research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- People with chronic sinusitis approved. This criteria contains the typical symptoms of chronic sinusitis, with or without appropriate medical treatment for more than 12 weeks. 2- Positive CT scan which indicates the opacity and swelling of the sinus mucosa. 3- Patients aged 18 to 60 years. 4- Fill the letter of satisfaction by the patient. No entry criteria: 1- Nose and sinus surgery in the last 5 years. 2- Antibiotic or topical corticosteroid use 15 days before entering the study. 3- Using oral corticosteroid 30 days before entering the study. 4- Moderate to severe asthma and mild asthma that has had an acute attack less than 30 days ago. 5- Aspirin- Exacerbated Respiratory Disease. 6- Active infections in the nose and sinuses. 7- Polyps in the nose. 8- Other diseases (neurogenic or psychiatric illness, malignancy, immunodeficiency) in the last 5 years, so that according to researcher, does not have the required qualifications to participate in the clinical trial. 9- Pregnancy.

Intervention groups

First group: recipient of Marjoram nasal spray, Decosalin nasal spray and Life style modification of Traditional Persian Medicine for 4 wk. Second group: recipient of Fluticasone nasal spray, Decosalin nasal spray and Life style modification of Traditional Persian Medicine for 4 wk. Third group: recipient of Sesame nasal spray, Decosalin nasal spray and Life style modification of Traditional Persian Medicine for 4 wk.

Main outcome variables

Comparison the scores of SNOT22 questionnaires before and after treatment in all three groups. Comparison the CT-scan scores before and after treatment in all three groups. Comparison the major and minor sinusitis symptoms in all three groups.

General information

Reason for update

Acronym

CRS

IRCT registration information

IRCT registration number: **IRCT20161022030439N2**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Seyed abdolreza Kamaneh

Name of organization / entity

Golestan univercity of medical scince

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

1991-01-21, 1369/11/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the influence of Marjoram oil Extract (Origanum Vulgare) in treatment of chronic rhinosinusitis without nasal polyps with fluticasone spray and sesame oil, concomitant with Life style modification of Traditional Persian Medicine, (a randomized, double-blind, clinical trial)

Public title

The influence of Marjoram oil Extract (Origanum Vulgare) in treatment of chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: 1- People with chronic sinusitis approved by the Academy of Otolaryngology-Head and Neck Ligation. This criteria contains the typical symptoms of chronic sinusitis, with or without appropriate medical treatment for more than 12 weeks. 2- Positive CT scan which indicates the opacity and swelling of the sinus mucosa. 3- Patients aged 18 to 60 years. 4- Fill the letter of satisfaction by the patient

Exclusion criteria:

Nose and sinus surgery in the last 5 years Antibiotic or topical corticosteroid use 15 days before entering the study Using oral corticosteroid 30 days before entering the study Moderate to severe asthma and mild asthma that has had an acute attack less than 30 days ago Aspirin- Exacerbated Respiratory Disease Active infections in the nose and sinuses Polyps in the nose Other diseases (neurogenic or psychiatric illness, malignancy, immunodeficiency) in the last 5 years, so that according to researcher, does not have the required qualifications to participate in the clinical trial Pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into 3 groups; cases and controls based on Simple Random Allocation (random numbers table)

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the drugs and the placebo are similar in size, shape, color and odor to prevent the bias in participants, clinical care provider and outcome evaluators. And each patient will get an unique code.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan Univercity of Medical Sciences

Street address
Phalsaphy complex, Shast kola Road

City
Gorgan

Province
Golestan

Postal code
4918936316

Approval date
2018-01-17, 1396/10/27

Ethics committee reference number
IR.GOUMS.REC.1396.241

Health conditions studied

1

Description of health condition studied
Chronic sinusitis

ICD-10 code
j32.9

ICD-10 code description
Sinusitis (chronic) NOS

Primary outcomes

1

Description
cough

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

2

Description
Posterior nasal discharge

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

3

Description
Need to blow nose

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

4

Description
sneezing

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

5

Description
Runny nose

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

6

Description
Nasal obstruction

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

7

Description
Loss of smell or taste

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

8

Description
Thick nasal discharge

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

9

Description
Post-nasal discharge

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

10

Description
Ear fullness

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

11

Description
Dizziness

Timepoint
Before and the end of the intervention

Method of measurement
SNOTE22 questionnaire

12

Description
Ear pain
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

13

Description
Facial pain/pressure
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

14

Description
Difficulty falling asleep
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

15

Description
Waking up at night
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

16

Description
Lack of a good night’s sleep
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

17

Description
Waking up tired
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

18

Description
Exhausted feeling during day
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

19

Description
Reduced productivity
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

20

Description
Reduce concentration
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

21

Description
Frustration or irritability
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

22

Description
sad
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

23

Description
Embarrassed
Timepoint
Before and the end of the intervention
Method of measurement
SNOTE22 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Prescribed in this group are:1- Marjoram oil nasal spray 2 puffs in each nostril Q12h for 4 wk. 2- Decosalin nasal spray 2 puffs Q12h for 4 wk. 3- Life style modification of Traditional Persian Medicine (LTPM). At the beginning, the Origanum Vulgare from the Gorgan Mountains collected its Voucher Number (1613) and dried. In order to prepare the drug, its semi-weighed was mixed with sesame oil and kept in an incubator at 50 ° C for 72 hours, then passed through the filter and marjoram oil

was extracted. In each drop of this extract, equivalent 0.017% of carvacrol is vailable. Life style modification of Traditional Persian Medicine contain: 1- avoiding supination and cool weather contact with the forehead and face 2- nasal irritation and sneezing at the first days of treatment 3- intense physical activities 4- reducing consumptions of some vegetables, such as garlic and onions, as well as date palm during an acute illness phase 5- limiting daily sleep 6- reinforcing the brain by inhaling rose, apple and saffron aromas 7- foot massage.

Category

Treatment - Drugs

2

Description

Prescribed in this group are: 1- Fluticasone nasal spray 2 puffs in each nostril Q12h for 4 wk. 2- Decosalin nasal spray 2 puffs Q12h for 4 wk. 3- Life style modification of Traditional Persian Medicine (LTPM). Life style modification of Traditional Persian Medicine contain: 1- avoiding supination and cool weather contact with the forehead and face 2- nasal irritation and sneezing at the first days of treatment 3- intense physical activities 4- reducing consumptions of some vegetables, such as garlic and onions, as well as date palm during an acute illness phase 5- limiting daily sleep 6- reinforcing the brain by inhaling rose, apple and saffron aromas 7- foot massage.

Category

Treatment - Drugs

3

Description

Prescribed in this group are: 1- Sesame oil nasal spray (placebo) 2 puffs in each nostril Q12h for 4 wk. 2- Decosalin nasal spray 2 puffs Q12h for 4 wk. 3- Life style modification of Traditional Persian Medicine (LTPM). Life style modification of Traditional Persian Medicine contain: 1- avoiding supination and cool weather contact with the forehead and face 2- nasal irritation and sneezing at the first days of treatment 3- intense physical activities 4- reducing consumptions of some vegetables, such as garlic and onions, as well as date palm during an acute illness phase 5- limiting daily sleep 6- reinforcing the brain by inhaling rose, apple and saffron aromas 7- foot massage.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hospital

Full name of responsible person

Mona Mazidi

Street address

5 Azar Hospital – 5 Azar Blvd

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Province

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4917761551

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Seyed Abdolreza Kamaneh

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available