Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of nasal spray based on herbal extracts (a traditional Persian medicine formulation) on the treatment of chronic rhinosinusitis, A multicentral randomized double blind placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation of the effect of nasal spray based on herbal extracts (a traditional Persian medicine formulation) on the treatment of chronic rhinosinusitis

Design

Randomized double-blind placebo controlled clinical trial on 80 patients, parallel group and Excel software will be used for randomization.

Settings and conduct

The location of the project is otolaryngology clinics of Valiasr hospital & Imam Ali hospital of Kazeroon. Patients with definite diagnosis of chronic rhinosinusitis entered the study and questionnaires completed for them. Patients were randomly divided into two intervention and control groups (n = 40). In the intervention group, patients treated for 3 weeks by nasal spray with 2 puffs each 8 hours and in the control group they use placebo. Patients, researchers and medical personnel are blinded in this study.

Participants/Inclusion and exclusion criteria

Chronic rhinosinusitis patients without polyposis more than 18 years, with Lund - Mckay more than 3 (moderate to severe rhinosinusitis), which after obtaining informed consent, were included in this research.In addition, patients with history of previous sinus surgery, pregnant or lactating mothers, Samter's triad patients (asthma, allergy and sensitivity to Aspirin, nasal polyposis) and those who are not consented to involved in this research excluded from the study.

Intervention groups

In the intervention group, the patients were treated for 3 weeks by herbal nasal spray with 2 puffs each 8 hours and in the control group they use placebo nasal spray which is similar to the intervention group. SNOT22 and RhinoQOL questionnaire at the end of the study were completed for the patients of both groups).

Main outcome variables

the score of symptoms of sinusitis (headache, cough, sneezing, PND, etc.) based on SNOT22 questionnaire; Score of quality of life of patients based on RhinoQOL questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121031011341N13**
Registration date: **2024-06-08, 1403/03/19**
Registration timing: **prospective**

Last update: **2024-06-08, 1403/03/19**
Update count: **0**

Registration date

2024-06-08, 1403/03/19

Registrant information

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Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of nasal spray based on herbal extracts (a traditional Persian medicine formulation) on the treatment of chronic rhinosinusitis, A multicentral randomized double blind placebo-controlled clinical trial

Public title

Evaluation the effect of nasal spray based on herbal extracts on the treatment of chronic rhinosinusitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic rhinosinusitis without nasal polyposis Lund- Mckay score more than 3 in PNS CT Scan Full consciousness and sign a written consent for participation in the study

Exclusion criteria:

Patients with history of previous sinus surgery Pregnant patients or breastfeeding mothers Patients with Samter triad (asthma, allergy to aspirin, nasal polyposis) People who refuse to be involved in this research study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **2**

placebo spray & herbal nasal spray

Randomization (investigator's opinion)

Randomized

Randomization description

The sample is determined by random block method with 4 blocks and using random numbers table. The block and allocation sequence for concealment will be carried out by the non - involved person in the study. the allocation ratio of the samples is one to one, and the drugs are based on the blocks and the allocation sequence will be assigned to the patients. A third person, other than the main researcher and patient, from the medical staff, enters the patients in sample study group as he does not know the details of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

it is a double blind study .after completion of consent form and initial knowledge of the research plan , patients will participate in the study , but considering that the drugs are in the same shape , they do not know which group they are in and are unaware of the details .the researcher is unaware of the details of the study and how individuals are assigned to the treatment and the control group .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Science

Street address

Vice-Chancellery of Research and Technology office, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶۷۱۳۴۸

Approval date

2024-01-14, 1402/10/24

Ethics committee reference number

IR.SUMS.REC.1402.472

Health conditions studied

1

Description of health condition studied

Chronic rhinosinusitis

ICD-10 code

J31.0

ICD-10 code description

Chronic rhinitis

Primary outcomes

1

Description

Sign & symptom of disease

Timepoint

3 weeks after intervention

Method of measurement

SNOT 22 questionnaire

2

Description
Quality of life of patients
Timepoint
3 weeks after intervention
Method of measurement
RhinoQOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients were treated for 3 weeks by nasal spray based on traditional persian medicine 2puff on each nostril for each 8 hours.
Category
Treatment - Drugs

2

Description
Control group: patients use placebo nasal spray which is similar in taste and odor with intervention group for 3 weeks by using 2 puffs in each nostril every 8 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ear, nose, throat clinic of Valiasr Hospital
Full name of responsible person
Soheil Motamed
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempur

Position
Assistant professor
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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