Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the effect of Xylitol nasal spray in treatment of patients with chronic rhinosinusitis

Protocol summary

Study aim
Determination of the efficacy of xylitol nasal spray in the treatment of patients with chronic rhinosinusitis

Design
A clinical trial with a control group, double blinded, randomized

Settings and conduct
This trial study was performed on 30 patients with chronic rhinosinusitis who referred to Alzahra Hospital Clinic. Then patients are divided into two groups randomly. The first group received either the nasal spray intervention xylitol and the second group or placebo nasal spray. Patients are visited on two occasions, on the first visit on arrival and on the second visit 30 days after treatment, on the first visit demographic information including age, sex, duration of illness, and BMI for patients is recorded, Then, after physical examination and endoscopic examination of the sinuses, the Lund Kennedy score is calculated by an ENT expert according to the endoscopic examination.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic rhinosinusitis; They had previously undergone sinus endoscopy and now need only non-surgical treatments; Exclusion criteria: Patients who have a history of allergic rhinitis, Asthma, Immunodeficiency, Cystic fibrosis, Primary pulmonary dyskinesia, Active bacterial or fungal infection and need antibiotics or antifungals; Have a history of head and neck radiation therapy; Now be a smoker; Pregnant people; Have granulomatous disease

Intervention groups
We have two groups. The first group received either the nasal spray intervention xylitol and the second group or placebo nasal spray.

Main outcome variables
Duration of illness; Lund Kennedy; SNOT 22 (Sino-nasal Outcome Test); Severity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N35**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**
Update count: **0**

Registration date
2020-04-11, 1399/01/23

Registrant information

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Name of organization / entity
Shahrekord University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-07, 1399/01/19

Expected recruitment end date
2020-05-03, 1399/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Xylitol nasal spray in treatment of patients with chronic rhinosinusitis

Public title
Effect of Xylitol nasal spray in treatment of chronic rhinosinusitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic rhinosinusitis Age over 18 years They had previously undergone sinus endoscopy and now need only non-surgical treatments.

Exclusion criteria:
Patients who have a history of allergic rhinitis, asthma, immunodeficiency, cystic fibrosis, primary pulmonary dyskinesia, active bacterial or fungal infection and need antibiotics or antifungals Patients who are unsatisfied with non-surgical treatment or want to have surgery again for any reason Have a history of head and neck radiation therapy Now be a smoker Pregnant people Have granulomatous disease

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample was randomly divided into two groups of 15 patients. Each envelope containing one of the two labels A and B represented one of the intervention groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
For the purpose of blinding, neither the patients nor the researchers were aware of the type of treatment each group received until the completion of the study. The treatments were divided into two groups as closed packages with codes A and B that were assigned to group A packages containing code A and group B packages containing code B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City
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Province
Isfehan

Postal code
7346181746

Approval date
2020-01-14, 1398/10/24

Ethics committee reference number
IR.MUI.MED.REC.1398.521

Health conditions studied

1

Description of health condition studied
Rhinosinusitis

ICD-10 code
J32.9

ICD-10 code description
Chronic sinusitis, unspecified

Primary outcomes

1

Description
Lund Kennedy Score

Timepoint
Before and after the study

Method of measurement
Lund Kennedy questionnaire

2

Description
SNOT 22 (Sino-nasal Outcome Test) score

Timepoint
Before the intervention and 30 days after the intervention

Method of measurement
SNOT 22 (Sino-nasal Outcome Test)

3

Description
Severe pain when pressing on the sinuses

Timepoint
Before and after the study

Method of measurement
VAS (Visual Analog Scale) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: xylitol nasal spray intervention group is given two puffs every 8 hours for 30 days.
Category
Treatment - Drugs

2

Description
Control group: The second group, or placebo, received normal saline two puffs every 8 hours for 30 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Ahmad Rezaeian
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Soffeh Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ahmad Rezaeian
Position
Assistant Professor of ear, nose and throat
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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