

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

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

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st_ansari.s@skums.ac.ir

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

Isfahan

Province

Isfahan

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

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Full name of responsible person

Ahmad Rezaeian

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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