

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between the effects of nasal lavage using solutions of hypertonic saline, isotonic saline and hypotonic saline in treating the symptoms of chronic sinusitis

Protocol summary

Summary

Nasal lavage as an adjuvant inexpensive and easy treatment treatment is used in the sinonasal diseases like sinusitis. Several papers have also reported clinical symptoms of sinus . Reviews of the studies suggest that there is not a single opinion concerning the superiority of one of the triple solutions of hypertonic saline, hypotonic saline or isotonic saline in treating the symptoms of sinusitis. This clinical trial study is on 185 patients with chronic sinusitis referred to Imam Khomeini and Apadana hospitals in Ahvaz. With a diagnosis of chronic sinusitis by an ear, nose and throat specialist and using the CT scan the patients have been selected. For collecting the data the necessary symptoms and information on the patients are recorded in a standard information gathering questionnaire. The patients are completely randomly divided into four groups. The first group will receive just medication; the second group will receive medication as well as nasal lavage or hyper saline; the third group will receive medication in addition to nasal lavage or isotonic saline; the fourth group will receive medication plus nasal lavage or hypotonic saline.then groups will compare in terms of treating the symptoms of sinusitis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021020320N2**

Registration date: **2015-07-02, 1394/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-02, 1394/04/11

Registrant information

Name

Somayeh Araghi

Name of organization / entity

ENT Department of the Jondishapour Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 9664

Email address

araghi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapor University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effects of nasal lavage using solutions of hypertonic saline, isotonic saline and hypotonic saline in treating the symptoms of chronic sinusitis

Public title

effects of nasal lavage using solutions of hypertonic saline, isotonic saline and hypotonic saline in treating the symptoms of chronic sinusitis

Purpose

Treatment
Inclusion/Exclusion criteria
inclusion criteria: chronic sinusitis
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information

Sample size
Target sample size: **185**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jondishapour Ahvaz University of Medical Sciences
Street address
Jondishapour Ahvaz University of Medical Sciences, Golestan
City
Ahvaz
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
ETh-022

Health conditions studied

1

Description of health condition studied
Chronic sinusitis
ICD-10 code
J32
ICD-10 code description
Chronic sinusitis

Primary outcomes

1

Description
Headache
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

2

Description
Discharge from the nose and throat
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

3

Description
Nasal obstruction
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

4

Description
Coughing
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

5

Description
Olfactory problems
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

6

Description
Feeling of fullness in the face
Timepoint
before treatment and 3 months later
Method of measurement
lack of the effect (1 score), minor effect (2 scores), the relative effect (3 scores) or the full effect (4 scores)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1- medication as well as nasal lavage of hypertonic saline

Category

Treatment - Drugs

2

Description

Intervention group 2-medication in addition to nasal lavage of isotonic saline

Category

Treatment - Drugs

3

Description

Intervention group 3- medication plus nasal lavage of hypotonic saline

Category

Treatment - Drugs

4

Description

Control group - just medication receive

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Somayeh Araghi

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

ENT Department, Imam Khomeini Hospital , 24 Metri

Avenue, Ahavz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor of Ahvaz Jondishapour 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

Jondishapour Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Somaye Araghi

Position

Resident

Other areas of specialty/work

Street address

ENT Department, Imam Khomeini Hospital, 24 Metri Street

City

Ahvaz

Postal code

Phone

+98 61 3333 9664

Fax

Email

savesina@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

ENT Department, Jondishapour University of Medical Sciences

Full name of responsible person

Somayeh Araghi

Position

Resident of ENT

Other areas of specialty/work

Street address

ENT Department, Imam Khomeini Hospital

City

Ahvaz

Postal code
Phone
+98 61 3333 9664
Fax
Email
savesina@yahoo.com
Web page address

Phone
00
Fax
Email
savesina@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Full name of responsible person
Dr. Somayeh Araghi
Position
Resident
Other areas of specialty/work
Street address
ENT Department, 24 Metri Avenue, Imam Khomeini
Hospital, Ahvaz
City
Ahvaz
Postal code

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