Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Outcome of usage of spray cryotherapy on management of healing in patients with nasal polyposis undergoing functional endoscopic sinus surgery.

Protocol summary

Summary

This is a prospective, controlled, randomized, clinical trial and aim of this study is evaluation of effect of spray cryotherapy (SCT) on management of healing in patients with nasal polyposis undergoing functional endoscopic sinus surgery (FESS). Inclusion criteria: patients with bilateral nasal polyposis who have indication for functional endoscopic sinus surgery; age between 18 to 70 years. Exclusion criteria: The patients with severe complications; People who do not have the consent to participate in the study; do not follow up. The sample size is 40 patients. Patients are randomly divided into two parallel groups as intervention and placebo groups. The randomization is doing with a randomization software. Intervention group are under treatment with SCT and placebo group is under treatment with normal saline spray after FESS. Recovery will be evaluated in both groups according to pre-prepared questionnaire after 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092012782N19**
Registration date: **2017-10-08, 1396/07/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-08, 1396/07/16

Registrant information

Name

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Isfahan University of Medical Sciences

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2016-12-31, 1395/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcome of usage of spray cryotherapy on management of healing in patients with nasal polyposis undergoing functional endoscopic sinus surgery.

Public title

Effect of spray cryotherapy on treatment of nasal polyposis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with bilateral nasal polyposis who have indication for functional endoscopic sinus surgery; age between 18 to 70 years. Exclusion criteria: The patients with severe complications; People who do

not have the consent to participate in the study; do not follow up.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Isfahan, Iran.

City
Isfahan

Postal code
7346181746

Approval date
2017-03-21, 1396/01/01

Ethics committee reference number
IR.MUI.REC.1396.30430

Health conditions studied

1

Description of health condition studied
Nasal Polyposis

ICD-10 code
J32

ICD-10 code description
Chronic sinusitis

Primary outcomes

1

Description
Recovery

Timepoint
Before intervention and 12 weeks after intervention

Method of measurement
Prepared questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Under treatment with Cryotherapy spray after endoscopic sinus surgery

Category
Treatment - Drugs

2

Description
Placebo group: Normal saline spray after endoscopic sinus surgery

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amin Hospital

Full name of responsible person
Ahmad Rezaeian

Street address
Amin Hospital, Isfahan, Iran.

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Isfahan University of Medical Sciences

Full name of responsible person
Dr Mansour Siavash

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Isfahan University of Medical Sciences, Isfahan, Iran.

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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
Vice chancellor for research,Isfahan 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

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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