

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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

Ali Mehrabi kushki

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 1510

##### Email address

mehrabim@mui.ac.ir

##### 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.

##### City

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

##### Street address

Isfahan University of Medical Sciences, Isfahan, Iran.

##### City

Isfahan

#### 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****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Ahmad Rezaeian

**Position**

Otorhinolaryngologist/ Assistant professor

**Other areas of specialty/work****Street address**

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Assistant professor of Otorhinolaryngology

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Isfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Responsible for research/Master of Science

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**Web page address****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*