

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effect of cryotherapy (cryoablation) of posterior nasal nerve on the treatment of patients with rhinitis

Protocol summary

Study aim

Determining the effect of cryotherapy of the posterior nasal nerve on the treatment of patients with rhinitis

Design

A clinical trial with single group comparing symptoms before and after cryotherapy of the posterior nasal nerve in 40 eligible patients with rhinitis.

Settings and conduct

Forty eligible patients referred to the ENT clinic of Baqiyatallah Hospital will be selected and the symptoms will be registered in 4 categories of absence, mild, moderate and severe according to the TNSS scoring system. After performing cryotherapy of PNN endoscopically using a cryonasal device, the researcher again will record the symptoms of the patients after performing cryotherapy at time intervals of 7 days later, one month later, three months later and six months later, using the TNSS scoring system.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years old; Diagnosis of rhinitis (allergic, non-allergic or a combination of both) by an ENT specialist; Failure to respond to treatment with conventional medical drugs for at least 3 months. Non-inclusion criteria: Patients with acute or chronic sinusitis; Medicinal rhinitis (medicamentosa); Presence of CSF rhinorrhea; Systemic diseases involving the sinonasal area.

Intervention groups

Performing cryotherapy of the posterior nasal nerve in patients with rhinitis who have not responded to treatment with conventional drugs.

Main outcome variables

Improving the symptoms of rhinitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220421054606N1**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**

Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name

Hossein Eshraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4022 6102

Email address

hossein.eshraghi313@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of cryotherapy (cryoablation) of posterior nasal nerve on the treatment of patients with rhinitis

Public title

Effect of cryotherapy (cryoablation) of posterior nasal nerve on rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years The diagnosis of rhinitis (allergic, non-allergic or a combination of both) was made by an ENT specialist based on history and examinations. Failure to respond to treatment with conventional medical drugs for at least 3 months

Exclusion criteria:

Patients with acute or chronic sinusitis Medicinal rhinitis (medicamentosa) Cerebrospinal fluid leakage in the form of CSF rhinorrhea Systemic diseases involving the sinonasal such as: granulomatous polyangiitis (Wegener), Sjögren's, cystic fibrosis (CF), primary ciliary movement disorder (PCD) History of frequent epistaxis, pregnancy and coagulation disorders Evidence of benign or malignant sinonasal neoplasms

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah Hospital; Azam dead end alley; South Sheikh Bahai street

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.047

Health conditions studied

1

Description of health condition studied

Allergic or non-allergic rhinitis or a combination of both

ICD-10 code

J30

ICD-10 code description

Vasomotor and allergic rhinitis

Primary outcomes

1

Description

Score of rhinitis symptoms based on TNSS (Total Nasal Symptom Score) questionnaire

Timepoint

Recording the severity of rhinitis symptoms at the beginning of the study (before the start of cryotherapy) and 7 days later, one month later, three months later and six months after cryotherapy of the posterior nasal nerve.

Method of measurement

TNSS (Total Nasal Symptom Score) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients with rhinitis who are over 18 years old and have not responded to conventional medical treatments for at least 3 months, in the clinic environment, under local anesthesia and during nasal endoscopy, cryotherapy (cryoablation) of the posterior nasal nerve by Cryonasal device is performed for them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT Clinic of Baqiyatallah Hospital

Full name of responsible person

Mohsen Saberi Isfeedvajani

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Baqiyatallah Hospital; Azam dead end alley; South
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

AbbasAli Imani Fooladi

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hossein Eshraghi

Position

ENT Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hossein Eshraghi

Position

ENT Resident

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, the data related to the main outcome (scoring of rhinitis symptoms based on the TNSS questionnaire before and after performing Cryotherapy) can be shared after de-identifying the subjects.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Study data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is possible to use the data and documents to conduct additional research related to the title of the study, provided the source and the names of the researchers of this study are mentioned.

From where data/document is obtainable

To receive study data and documents, they can send their request to the following email:
Hossein.eshraghi313@gmail.com

What processes are involved for a request to access data/document

To receive study data and documents, they can send their request to the following email:
Hossein.eshraghi313@gmail.com After sending an email and checking their request by the study researchers, if there is no problem, we will try to provide them with the data in a short period of time.

Comments