

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of fibrin glue autolog on amandation tissues and relapse polyps on sinusoidal patients after (Functional Endoscopic Sinus Surgery) FESS

Protocol summary

Study aim

Evaluation the effect of fibrin glue autolog on amandation tissues and polyps relapse on sinusoidal patients after (Functional Endoscopic Sinus Surgery) FESS

Design

Clinical trial with control group, parallel groups with One-blind randomized trial, phase 3-2 on 32 patients and andomized with table numbers

Settings and conduct

This study will be performed on patients referred to the ENT department of subspecialty clinic of Ghaem Hospital in Mashhad, who have bilateral sinus nasal polyps and FESS candidates surgery. The study is monocentric and single-blind while the patients will not be aware of the allocation which type of solution to each side of the nose.

Participants/Inclusion and exclusion criteria

Bilateral sinus nasal polyps and the same drug treatment and lack of immunological diseases prone to improper wound healing, no history of abnormal bleeding or thrombocytopenia

Intervention groups

During this study, after endoscopic sinus surgery and removal of bilateral polyps, on the surgical bed one cc of normal saline solution is poured in a side of the patient's nose as the control group and on the other side of the same patient's nose as the intervention group One cc of fibrin glue solution prepared from the individual's own serum will be poured into opened sinuses by syringe under the endoscope.

Main outcome variables

Improvement of Sinonazal Polyposis Symptoms after FESS surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038763N4**

Registration date: **2022-04-25, 1401/02/05**

Registration timing: **prospective**

Last update: **2022-04-25, 1401/02/05**

Update count: **0**

Registration date

2022-04-25, 1401/02/05

Registrant information

Name

mehdi bakhshae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3492

Email address

mehbakhsh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fibrin glue autolog on amandation tissues and relapse polyps on sinusoidal patients after (Functional Endoscopic Sinus Surgery) FESS

Public title

Evaluation of the effect of fibrin coagulation solution on improving nasal polyps

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Bilateral nasal sinus polyp Identical drug treatment in patients Satisfaction to enter the study

Exclusion criteria:

Presence of enterocanal polyps Unilateral polyp Immunological diseases prone to improper wound healing History of abnormal bleeding or thrombocytopenia History of previous sinus surgery

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, a list of patients who met the inclusion criteria is prepared and 32 patients will be selected using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study would be performed with the complete consent of the patients while the patient does not know which side of the nose is treating with control solution and which side of the nose is getting intervention solution.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.MUMS.REC.1401.017

Health conditions studied

1

Description of health condition studied

Sinonazal polyps

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes

1

Description

Improvement of Sinonazal Polyposis Symptoms

Timepoint

One week, one month and three months after surgery

Method of measurement

Lund-kennedy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: During this study, after sinus endoscopic surgery and removal of bilateral polyps, the surgical environment on one side of the patient's nose one cc of normal saline solution is poured inside the nose and the open sinuses by syringe under endoscopic vision.

Category

Placebo

2

Description

Intervention group: During this study, after endoscopic sinus surgery and removal of bilateral polyps, the surgical environment on the other side of the same patient's nose received one cc of fibrin coagulation solution prepared from the individual's own serum is poured inside the nose and sinuses opened by a syringe under endoscopic vision.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mehdi Bakhshaei

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi Bakhshaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available