Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Combined serum and fluticasone in chronic rhinosinusitis with polyposis in post op FESS patients

Protocol summary

Study aim

Effect of Combined serum (betamethasone, dexamethasone, bromhexine N/S) with fluticasone spray and N/S on 200 postoperative CRS patients with polyposis after FESS surgery

Design

controlled, single-blind, randomized, phase 2 clinical trial on 200 patients. The rand function of Excel software was used.

Settings and conduct

In this study, all patients referred to the clinic of Masih-Daneshvari Hospital with the diagnosis of chronic rhinosinusitis and polyposis will be divided into two randomized groups. None of the patients know the group they will be in, but the research team will be aware of it and the type of treatment. Patients will come back to the clinic one week after the surgery and according to the type of their group, they will receive the relevant interventional treatment for 3 weeks. Also, the Persian version of the SNOT-22 questionnaire, whose validity and reliability have been confirmed, will be used before and after the treatment. A questionnaire that measures the quality of life related to nose and sinus diseases with total scores between 0 and 110 and each item is graded on 6 levels (0-5).

Participants/Inclusion and exclusion criteria

Including criteria: Patients aged 18 to 70 with chronic rhinosinusitis who undergo endoscopic surgery due to nasal polyposis. Excluding criteria: Asthma, Severe systemic problems such as Heart Failure and Diabetes, Pregnancy, Cystic Fibrosis, Malignancies

Intervention groups

In the first group, at first, 10CC of mixed serum (one ampoule of betamethasone, dexamethasone, and bromhexine dissolved in a liter of normal saline washing serum) was poured into each nostril, then repeated every 12 hours. In the second group, at first 10CC normal saline serum was poured into each nostril, then fluticasone sprays 1 puff every 12 hours will be used.

Main outcome variables

Age, gender, endoscopic status, quality of life; before and after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191009045040N1**
Registration date: **2022-12-17, 1401/09/26**
Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**
Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name
Seyed amir ali Safavi naini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2207 2955
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

2022-12-22, 1401/10/01

Actual recruitment end date

2023-01-21, 1401/11/01

Trial completion date

2023-01-21, 1401/11/01

Scientific title

Effects of Combined serum and fluticasone in chronic rhinosinusitis with polyposis in post op FESS patients

Public title

Effects of Combined serum and fluticasone in chronic rhinosinusitis with polyposis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 18 and 50, with chronic rhinosinusitis with polyposis

Exclusion criteria:

without mucociliary disease, heart disease, diabetes, and no history of malignancy

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Masih Daneshvari of Shaheed Beheshti University of Medical Sciences

Street address

Daranad st.

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.SBMU.NRITLD.REC.1401.005

Health conditions studied

1

Description of health condition studied

Nasal polyp

ICD-10 code

J33

ICD-10 code description

Nasal polyp

2

Description of health condition studied

Chronic sinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Symptoms of rhinosinusitis include; Sneezing, runny nose, coughing, post-nasal discharge, thick nasal discharge, dizziness, ear fullness, pain and pressure in the ears, pain and pressure in the face, lack of taste or smell, nasal obstruction/congestion.

Timepoint

21 days after treatment

Method of measurement

SNOT22 score

Secondary outcomes

empty

Intervention groups

1

Description

BD nasal irrigation with N/S& DeXMT (16mg) & BeTMT(8mg) & BrMHX (4mg)

Category

Treatment - Drugs

2

Description

Control group: Fluticasone spray +BD nasal irrigation with N/S

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari hospital

Full name of responsible person
Amirali Safavi

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Darabad st.

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Md.amirali.safavi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. afshin Zarghi

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Velenjak.

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1985717434

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Email
zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Safavi

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

Contact

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Part of the data, such as information related to the main outcome or similar, can be shared.
When the data will become available and for how long
1 year after publication
To whom data/document is available
Dr. Jahangir Ghorbani Dr. Ali Safavi
Under which criteria data/document could be used
Unknown
From where data/document is obtainable
Dr. Ali Safavi
What processes are involved for a request to access data/document
Unknown
Comments