

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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)

##### Phone

+98 21 2207 2955

##### Email address

md.safavi.naini@gmail.com

##### 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

**Street address**

Darabad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 912 838 4529

**Email**

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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Phone**

+98 21 2243 9780

**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

**Street address**

Darabad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2627 1000

**Email**

md.safavi.naini@gmail.com

## Person responsible for scientific 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

**Street address**

Darabd st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2712 1000

**Email**

Md.safavi.naini@gmail.com

## Person responsible for updating data

### 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

**Street address**

Darabad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2627 1000

**Email**

Md.safavi.naini@gmail.com

**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**