

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Comparison of results of frontal sinus surgery with direct injection of Corticosteroid (Triamcinolone) and foam gel containing Corticosteroid (Triamcinolone)

#### Protocol summary

##### Study aim

Comparison of results of frontal sinus surgery with direct injection of Corticosteroid (Triamcinolone) and foam gel containing Corticosteroid (Triamcinolone)

##### Design

The study is a randomized, clinical trial consisting of 36 patients in 2 parallel groups with a double-blind design

##### Settings and conduct

Tabriz Sina hospital, endoscopic sinus surgery

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: Age of 18 to 65 years, Chronic rhinosinusitis as defined by the American Academy of Otolaryngology, patients have proved rhinosinusitis by CT-scan. Exclusion criteria include: Patients who are taking daily corticosteroid drugs, Pregnant patient, Existence of any polyp in the nasal cavity, Patient unwillingness to continue participating in the clinical trial

##### Intervention groups

One group of patients with chronic rhinosinusitis with bilateral polyposis received Triamcinolone impregnated gel foam as a nasal dressing and the other group received a topical injection of Triamcinolone

##### Main outcome variables

The rate of satisfaction, Inflammation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211218053446N1**

Registration date: **2021-12-28, 1400/10/07**

Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**

Update count: **0**

##### Registration date

2021-12-28, 1400/10/07

##### Registrant information

###### Name

Saleh jalili

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3334 7054

###### Email address

mehr\_mousavi@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-01-05, 1400/10/15

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of results of frontal sinus surgery with direct injection of Corticosteroid (Triamcinolone) and foam gel containing Corticosteroid (Triamcinolone)

##### Public title

Triamcinolone injection in frontal sinus surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age of 18 to 65 years Chronic rhinosinusitis as defined by

the American Academy of Otolaryngology patients have proved rhinosinusitis by CT-scan

**Exclusion criteria:**

Patients who are taking daily corticosteroid drugs  
Pregnant patient Existence of any polyp in the nasal cavity  
Patient unwillingness to continue participating in clinical trial

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, individuals were assigned to two groups using the permutation block method. In this method, A represents the individual receiving the foam gel containing Triamcinolone and B represents the individual in the topical Triamcinolone group. Considering the quadruple block; they were classified into AABB, ABAB, ABBA, BAAB BBAA, and BABA permutations, and by random selection from permutation patients were classified.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The treatment assessor and the statistical analyst will not be aware of the allocation of intervention until the end of the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz Medical School

**Street address**

International Relations Office, No 2 Central Building,  
Tabriz University of Medical Sciences, University  
Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Approval date**

2020-10-26, 1399/08/05

**Ethics committee reference number**

IR.TBZMED.REC.1399.756

**Health conditions studied**

**1**

**Description of health condition studied**

Chronic rhinosinusitis

**ICD-10 code**

J32.9

**ICD-10 code description**

Chronic sinusitis, unspecified

**Primary outcomes**

**1**

**Description**

Inflammation

**Timepoint**

1 month, 3 months, 6 months

**Method of measurement**

Physical Examination

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Triamcinolone impregnated gel foam  
nasal dressing

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Topical injection of Triamcinolone

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tabriz Sina Hospital

**Full name of responsible person**

Dr Mehrnoosh Mousaviagdas

**Street address**

Tabriz Sina Hospital, Azadi Street, Tabriz

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Tabriz  
**Province**  
East Azarbaijan  
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5163639888  
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mehr\_mousavi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr.Masood Naderpour  
**Street address**  
Department of Otolaryngology, Imam Reza Hospital,  
Golgasht Street, Tabriz  
**City**  
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East Azarbaijan  
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5166614756  
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**Email**  
info@imamreza.tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz University of Medical Sciences

#### Proportion provided by this source

10

#### 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. Mehrnoush Mousavi Aghdas  
**Position**  
Otolaryngorhinologist  
**Latest degree**

Specialist

#### Other areas of specialty/work

Ear, Nose, and Throat

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Tabriz University of Medical Sciences, Daneshgah  
street, Tabriz, Iran

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## Person responsible for scientific inquiries

#### Contact

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Otolaryngorhinologist  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
saleh jalali  
**Position**  
Resident of ENT  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Ear, Nose, and Throat  
**Street address**  
ENT ward, Emam Reza Hospital, Gholghasht Street,  
Azadi Street, Tabriz  
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East Azarbaijan  
**Postal code**  
5166614756  
**Phone**  
+98 41 3334 7054  
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shayan.jj1370@gmail.com

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

No - There is not 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**

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**

A portion of the data that represents the final outcome

### **When the data will become available and for how long**

Access will be 6 months after the results are printed

### **To whom data/document is available**

Otolaryngology specialists in coordination with the presenter

### **Under which criteria data/document could be used**

The use of data to improve patients' treatment processes is safe

### **From where data/document is obtainable**

Person responsible for updating study information

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

Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

### **Comments**