Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Masood Naderpour
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Department of Otolaryngology, Imam Reza Hospital, Golgasht Street, Tabriz
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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
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
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Otolaryngorhinologist
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Specialist
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Person responsible for updating data

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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