Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of Tacrolimus drop in preventing the recurrence of nasal polyps in patients with chronic rhinosinusitis after endoscopic sinus surgery

Protocol summary

Study aim
Determining the effect of tacrolimus drops in preventing the recurrence of nasal polyps in patients with chronic rhinosinusitis after endoscopic sinus surgery.

Design
The clinical trial has a control group, with parallel groups, double-blind, randomized and using a randomization software, a total of 20 patients in two groups (tacrolimus group and betamethasone group) are examined.

Settings and conduct
The current study is a randomized clinical trial in Shafa Kerman Hospital with the research population of patients with chronic rhinosinusitis with polyps who are candidates for endoscopic sinus surgery. Before surgery, patients will undergo CT scan evaluation using Lund-Mackay criteria and endoscopic evaluation with Lund-Kennedy criteria. After surgery, patients are randomly assigned to two groups receiving tacrolimus 0.03% drops and one group receiving corticosteroid drops. Patients will be evaluated endoscopically at intervals of 3, 6 and 9 months after surgery.

Participants/Inclusion and exclusion criteria
The inclusion criteria: 1. Patients referred to Shafa Kerman Hospital in 1401 who were candidates for surgery due to chronic rhinosinusitis with polyps 2. Informed consent to enter the study The exclusion criteria: 1. Age less than 18 years 2. Suffering from genetic diseases including Ciliary Dyskinesia or Cystic Fibrosis 3. Recurrence of polyps less than 3 months after surgery

Intervention groups
intervention group (use of topical tacrolimus 0.03% drops to determine the effect in preventing the recurrence of nasal polyps) and control group (routine drug treatment - corticosteroid drops called betamethasone) Medicines are continued daily (5 drops every morning) until the end of the study (9 months).

Main outcome variables
rate of clinical improvement; sinus endoscopic evaluation score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221206056721N1**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date
2023-01-22, 1401/11/02

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-08, 1401/10/18

Expected recruitment end date
2023-05-19, 1402/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Tacrolimus drop in preventing the recurrence of nasal polyps in patients with chronic rhinosinusitis after endoscopic sinus surgery

Public title
Effect of Tacrolimus drop in Nasal Polyp Recurrence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Shafa Kerman Hospital in 1401 who are candidates for surgery due to chronic rhinosinusitis with polyps (patients who have not responded to common treatments including broad-spectrum antibiotics, inhaled steroids, and short-term courses of oral steroids) Informed consent to enter the study
Exclusion criteria:
Age less than 18 years Suffering from genetic diseases including Ciliary Dyskinesia or Cystic Fibrosis Recurrence of polyps less than 3 months after surgery Patients who were in the intervention group and showed sensitivity to tacrolimus drops. Patients who did not refer for follow-up Lack of informed consent to enter the study
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: simple randomization Using random allocation software, patients were randomly assigned to one of two intervention and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants (patients who are candidates for surgery due to chronic rhinosinusitis with polyps), clinical caregivers In both groups, in the form of drops with the same shape, color and dosage for 9 months, so that patients and doctors will be unaware of how the drops are allocated to the intervention and control groups, and the drops will be numbered, which only the data analyzer will know about the numbering.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Scieces
Street address
Hospital Shafa, Kerman University of Medical Sciences
City
Kerman
Province
Kerman
Postal code
7618751151
Approval date
2023-01-16, 1401/10/26
Ethics committee reference number
IR.KMU.REC.1401.367

Health conditions studied

1

Description of health condition studied
Nasal polyps
ICD-10 code
J33.0
ICD-10 code description
Polyp of nasal cavity

2

Description of health condition studied
Chronic rhino sinusitis
ICD-10 code
J32.9
ICD-10 code description
Chronic sinusitis, unspecified

Primary outcomes

1

Description
Lund-Kennedy Score
Timepoint
Patients of both groups were followed up at intervals of 3 months, 6 months, and 9 months after surgery, and the Lund-Kennedy score was calculated during endoscopic examination.
Method of measurement
Method of measurement: endoscopy and unit of measurement: score

Secondary outcomes

1

Description
Lund-Mckay score
Timepoint
Patients of both groups underwent follow-up at intervals of 3 months, 6 months, and 9 months after surgery.
Method of measurement
Method of measurement: CT Scan and unit of measurement: score

Intervention groups

1

Description
Intervention group: In the intervention group, tacrolimus 0.03% topical drops are prescribed. These drugs are continued daily until the end of the study (9 months). Patients who are treated with tacrolimus drops, if they experience side effects and sensitivity during the first, third and seventh days after the start of treatment, they will be excluded from the study and treated with steroid drops. It should be noted that Prograf ampoules (5mg/1ml) are used to make tacrolimus drops. In this formulation, 3 ampoules with a volume of 3 ml containing 15 mg of tacrolimus are mixed with 47 ml of sterile phosphate buffer and the resulting solution is divided into sterile 5 ml drop containers and will be available to patients. These drops should be stored in a refrigerator at a temperature of 4 degrees Celsius.
Category
Treatment - Drugs

2

Description
Control group: In the control group, betamethasone corticosteroid drops (manufacturer of Sinadaro) are prescribed (routine and usual treatment). These drugs will be continued daily (5 drops every morning) until the end of the study (9 months). Patients who are treated with tacrolimus drops, if they experience side effects and allergies during the first, third and seventh days after the start of treatment, they will be excluded from the study and treated with corticosteroid drops (betamethasone).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Jalali
Position
resident
Latest degree
Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
here is no further information
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