

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A randomized controlled trial of low dose MACROLIC (AZITHROMYCIN) in the prevention of symptom relapse in CHRONIC RHINOSINUSITIS after endoscopic surgery -EMAM KHOMEINI HOSPITAL 2010-2012

Protocol summary

Summary

We want to study azithromycin effect on symptom relief of chronic rhinosinusitis after surgery. Inclusion criteria: chronic rhinosinusitis with or without polyposis after endoscopic surgery exclusion criteria : immunodeficiency , cystic fibrosis study population : known cases of rhinosinusitis after endoscopic surgery After endoscopic surgery , control group will receive standard conventional treatment (fluticasone spray + normal saline washing TDS) . intervention group will receive conventional treatment (fluticasone spray + normal saline washing TDS)+ azithromycin 250 mg daily for 3 month Before and 3 month after surgery patients will fill SNOT 22 standard questionnaire .and outcomes(symptom relief) will compare between these 2 groups.

General information

Acronym

Azithro Trial Sinusitis (ATS)

IRCT registration information

IRCT registration number: **IRCT201105146468N1**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Amin Amali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

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a_amali@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-06-04, 1390/03/14

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized controlled trial of low dose MACROLIC (AZITHROMYCIN) in the prevention of symptom relapse in CHRONIC RHINOSINUSITIS after endoscopic surgery -EMAM KHOMEINI HOSPITAL 2010-2012

Public title

Azithromycin effect on chronic sinusitis symptoms after endoscopic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : chronic rhinosinusitis with or without polyposis after endoscopic surgery exclusion criteria : immunodeficiency ; cystic fibrosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Science

Street address

16 AZAR street; TEHRAN

City

TEHRAN

Postal code**Approval date**

2011-04-11, 1390/01/22

Ethics committee reference number

90/130/42/3

Health conditions studied1**Description of health condition studied**

chronic sinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes1**Description**

symptom severity

Timepoint

before and 3 month after initiation of therapy

Method of measurement

patients will fill SNOT22 symptom questionnaire

Secondary outcomes1**Description**

diarrhea,rash,abdominal pain,palpitation,melena

Timepoint

during therapy

Method of measurement

patients symptoms and signs

Intervention groups1**Description**

intervention : azithromycine 250 mg daily for 3 month + conventional therapy (fluticasone spray + normal salin washing TDS) control : fluticasone spray + normal salin washing TDS

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

VALIASR ENT center. EMAM KHOMEINI hospital

Full name of responsible person

DR.AMIN AMALI

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masud Younesian

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty