

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Email address

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 committees

1

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

90/130/42/5

Health conditions studied

1

Description of health condition studied

chronic sinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

symptom severity

Timepoint

before and 3 month after initiation of therapy

Method of measurement

patients will fill SNOT22 symptom questionnaire

Secondary outcomes

1

Description

diarrhea,rash,abdominal pain,palpitation,melena

Timepoint

during therapy

Method of measurement

patients symptoms and signs

Intervention groups

1

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 centers

1

Recruitment center

Name of recruitment center

VALIASR ENT center. EMAM KHOMEINI hospital

Full name of responsible person

DR.AMIN AMALI

Street address

EMAM KHOMEINI hospital; KESHAVARZ avenue; TEHRAN

City

TEHRAN

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masud Younesian

Street address

POORSINA street ; TEHRAN

City

Tehran

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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

DR.Amin Amali

Position

ENT professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Narges Hassanpoor

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MD.MPH

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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