Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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 rhinosinositis 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 rhinosinositis 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/ɔ

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 questionnare

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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Tehran University of Medical Sciences

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