

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Antibiotic prophylaxis roles in success of myringoplasty in patients with eardrum perforation

Protocol summary

Summary

In this study 200 patients that are candidates for myringoplasty will be chosen and divided into two groups randomly. In group A 1gr sefazolin an hour before beginning of surgery and every 6 hours after surgery until 24 hours will be given to the patients and in visit of patients 1,2,4 and 8 weeks after surgery ,if no infection is seen, no antibiotics will be administered . in group B ,in addition to the mentioned protocol (1gr sefazolin an hour before beginning of surgery and every 6 hours after surgery until 24 hours and then), 500mg cephalixin capsule every 6 hours until 10 days will be given to the patients. Ear infections will be checked in first, second, forth and eighth week after surgery and results will be accumulated in checklists with all information of patients including age, sex, size of eardrum perforation (total, subtotal, half, lesser than half), duration of surgery, duration of dry ear before surgery (2 months, 2-6 months, 6-12 months, more than one year), tympanosclerosis, ear discharge, type and amount of used antibiotics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105222821N5**

Registration date: **2011-06-11, 1390/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-11, 1390/03/21

Registrant information

Name

Seyed Javad Seyed Toutouchi

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 9435

Email address

totonchis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2010-01-21, 1388/11/01

Expected recruitment end date

2011-06-21, 1390/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibiotic prophylaxis roles in success of myringoplasty in patients with eardrum perforation

Public title

Antibiotic prophylaxis roles in success of myringoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1.patients with eardrum perforation, 2. no discharge of ear for 2 months, 3.no other pathology in middle ear. Exclusion criteria: 1. patients with active ear discharge, 2. other pathology of middle ear, 3.systemic diseases such as diabetes, 4.no satisfaction of patient

Age

From **18 years** old to **60 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 200

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences

City
Tabriz

Postal code
516568

Approval date
2010-06-29, 1389/04/08

Ethics committee reference number
5/4/2393

Health conditions studied

1

Description of health condition studied
chronic otitis media

ICD-10 code
H65

ICD-10 code description
Nonsuppurative otitis media

Primary outcomes

1

Description
eardrum healing

Timepoint
8 weeks

Method of measurement

examination and audiometry

Secondary outcomes

1

Description
infection of ear

Timepoint
1, 2, 4, 8 weeks

Method of measurement
examination and otoscopy

Intervention groups

1

Description
Group A: 1gr. sefazolin 1 hour before beginning of surgery and every 6 hours after surgery until 24 hours

Category
Treatment - Drugs

2

Description
Group B: 1gr. sefazolin 1 hour before beginning of surgery and every 6 hours after surgery until 24 hours and then 500mg cephalexin capsule every 6 hours until 10 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Seyed Javad Seyed Toutouchi

Street address
ENT Department, Emam Reza Hospital

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ali Meshkini

Street address
Faculty of Medicine

City
Tabriz

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
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
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Full name of responsible person
Atefe Nourmohamadi

Position
Medical Student

Other areas of specialty/work

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Otolaryngologist, Associate

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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