

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The treatment effect of Ceftizoxime powder and clotrimazole ointment on fungal otitis media

Protocol summary

Summary

This study will be performed on 80 patients with Otomycosis accompanied ruptured tympanic membrane in ENT clinic of Ayatollah Rouhani Hospital, Babol. After sampling, the expansions of ear pus will be performed on slides, immediately; and then will be stained by Gram method. In addition; Samples will be inoculated on the blood agar and chocolate agar medium, respectively at 37 °. The negative result for bacteria and a positive direct smear result (true or false mycelium and yeast) infection will be inserted in the otomycosis. Fungi will be diagnosed by conventional methods. Patients randomly will be divided into two groups, group 1: topical clotrimazole in the ear canal, after suction clearance. Group 2: topical clotrimazole and ceftizoxime powder in the ear canal, after suction clearance. All patients re exam after 2 weeks. Both Clinical specialist and laboratory scientists will not be informed the results of them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082313136N4**

Registration date: **2016-10-13, 1395/07/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-13, 1395/07/22

Registrant information

Name

Saeid Mahdavi Omran

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 9936

Email address

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences, Vice president for research and technology

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The treatment effect of Ceftizoxime powder and clotrimazole ointment on fungal otitis media

Public title

The effect clotrimazole ointment comparison to Ceftizoxime powder and clotrimazole ointment in the treatment of patients with fungal otitis media

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with otomycosis accompanied with ruptured tympanic membrane. Exclusion criteria: Patients with immunosuppression; Uncontrolled diabetic patients; Bacterial otitis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Grouping can be done using random numbers table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz St.

City

Babol

Postal code

47176-47745

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

mubabol.Rec.1395.28

Health conditions studied**1****Description of health condition studied**

Middle ear infection

ICD-10 code

H66

ICD-10 code description

Acute suppurative otitis media

Primary outcomes**1****Description**

The survey of clinical symptoms (pain, swelling, discharge and itching)

Timepoint

2 weeks after start of treatment

Method of measurement

Clinical and Laboratory

Secondary outcomes**1****Description**

Sensitivity to drug(s)

Timepoint

2 weeks after start of treatment

Method of measurement

Patient complaints and investigation by a physician

Intervention groups**1****Description**

Group 1: Suction clearance and once a layer of topical Clotrimazole cream 1% made by Pars Daru pharmaceutical corporation in the ear canal

Category

Treatment - Drugs

2**Description**

Group 2: Use of suction clearance and once a layer of topical clotrimazole (made by Pars Daru Pharmaceutical Corporation) and Ceftizoxime powder (made by Jaber ebn e Hayan Pharmaceutical corporation) in the ear canal by insufflation (after the use of clotrimazole)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rouhani Hospital, Babol

Full name of responsible person

Dr. Keyvan Kiakojuri, ENT specialist

Street address

Ganj Afrooz St.

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Ganj Afrooz St.

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Babol 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

Babol University of Medical Sciences

Full name of responsible person

Saeid Mahdavi Omran

Position

Ph. D and Scientific Board

Other areas of specialty/work

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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