# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**

s.mahdavi@mubabol.ac.ir

**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 immunosuppresion; 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 survay 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 insuflation (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**
**Street address**
Ganj afrooz St.
**City**
Babol
**Postal code**
4717647745
**Phone**
+98 11 3219 9936
**Fax**
**Email**
s.mahdavi@mubabol.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Dr. Keyvan Kiakojuri
**Position**
Fellow on Otolgy
**Other areas of specialty/work**
**Street address**
Ganj Afrooz St.
**City**
Babol
**Postal code**
4717647745
**Phone**
+98 11 3219 9936
**Fax**
**Email**
kia_ko13358@yahoo.com
**Web page address**

## Person responsible for updating data

**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**
**Street address**
Ganj Afrooz St.
**City**
Babol
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**Phone**
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s.mahdavi@mubabol.ac.ir
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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*