

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of clotrimazole 1% on recurrence of Otomycosis after treatment.

Protocol summary

Summary

The purpose of the present study is assessing the effectiveness of clotrimazole in preventing relapse of Otomycosis. In this study, at least 300 patients with Otomycosis will be placed in two groups; case (with the administration of clotrimazole) and control (without administration of clotrimazole). In this study, all patients with suspected Otomycosis referred to ear, nose and throat of Ayatollah Rouhani Hospital of Babol (one center) are enrolled. The absence of fungal infection and perforation in tympanic membrane may be excluded. Discharge will be removed using a sterile speculum for the ear for direct examination and culture on medium. In case with a positive result of fungal in direct examination, as a person with Otomycosis (inclusion criteria) will be considered. These people will be placed in two groups, randomly using sealed envelope. In case patients, after the initial treatment (as symptoms deleted, maximum in 2 weeks) immediately entered into the treatment phase; for this purpose a solution of clotrimazole 1% manufacturing pharmaceutical company Pars Daro for 1 month and 3 times a week, 2-3 drop per day will be used. Patients in the control group after treatment to prevent recurrence of Otomycosis will not use any drug. Recurrence rate of Otomycosis will be determined after three months with clinical and laboratory re-examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040513136N3**

Registration date: **2016-02-09, 1394/11/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

Name

Saeid Mahdavi Omran

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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s.mahdavi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2018-02-03, 1396/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of clotrimazole 1% on recurrence of Otomycosis after treatment.

Public title

The effect of clotrimazole on prevention of Otomycosis.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Otomycosis (Direct examination, or sometimes culture result). Exclusion criteria: Tympanic perforation.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

There is any study in Iran.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol, Ganj Afroz Street

City

Babol

Postal code

4717647745

Approval date

2015-12-15, 1394/09/24

Ethics committee reference number

6446/30/P/J

Health conditions studied

1

Description of health condition studied

Otomycosis

ICD-10 code

H62.2

ICD-10 code description

B36.9

Primary outcomes

1

Description

Recurrence

Timepoint

3 month

Method of measurement

Patient complaints and clinical examination

Secondary outcomes

1

Description

None

Timepoint

None

Method of measurement

None

Intervention groups

1

Description

Case group: After initial treatment and clinical survey (after 2 weeks), Clotrimazole 1% drop, manufacture by pharmaceutical company- Pars Daro, 2-3 drops /day, 3 times/ week, for 1 month will be use.

Category

Treatment - Drugs

2

Description

Control group: These pateints will not received any drug to prevent recurrence after treatment, But refereed after 2 weeks for treatment result by clinical survey.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Dr. Keyvan Kiakojouri

Street address

Babol, Ganjafrooz 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. Bijani
Street address
 Ganjafrooz 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
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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