Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

The purpose of the present study is assessing the effectiveness of clotrimazole in preventing relapse is Otomycosis. In this study, at least 300 patients with Otomycosis will be place in two groups; case (with the administration of clotrimazole) and control (without administration of clotrimazole). In this study, all patients with suspected to 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 peoples 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 for 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)

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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 reccurence 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 Afrooz 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