Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of two methods of healing Otomycosis using clotrimazole topical povidone iodine therapy

Protocol summary

Summary

This single-blind clinical trial will be performed on 204 patients with confirmed diagnosis of otomycosis who visit the special ENT clinic of Imam Reza and Valiasr hospitals affiliated to Birjand University of Medical Sciences during the second half of 1393 (hijri). In case there are clinical symptoms such as pain, pruritus, extra mass in external ear canal, and discharge, the patient will be regarded as suspect of otomycosis whereupon drainage will be sampled in a sterilized manner. After the KOH smear is prepared and fungal elements are observed, otomycosis will be confirmed. Patients will enter the study upon informed consent and will be allocated to the control (local chloroimidazole drop) or case (betadin solution) groups through randomized blocking. Patients will be examined by an ENT specialist unaware of the treatment 4, 10 and 20 days after intervention. Upon definite response, treatment will stop. Otherwise, treatment will continue. Non-response after 20 days will be considered as treatment-resistant, and treatment will continue by tolnaftate and violet de gentian diets.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014123020484N1**
Registration date: **2015-12-03, 1394/09/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-03, 1394/09/12

Registrant information

Name

Mohammad Hasan Namaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of healing Otomycosis using clotrimazole topical povidone iodine therapy

Public title

External ear fungal infection treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ear pain or pruritus; existence of clinical findings of skin erythema in external ear canal; ear occlusion along with hearing loss and discharge; discharge of puss from ear in recent 7 days; positive laboratory report confirming otomycosis. Exclusion criteria: media otitis along with stenosis in external ear canal; chronic era discharge; a history of ear surgery; a history of anti-fugnal and corticosteriods treatment;

external ear anomaly; perforation of tympanic membrane,

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **204**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Birjand University of Medical Sciences
Street address
South Khorasan- Birjand University of Medical Sciences
City
Birjand
Postal code
Approval date
2013-12-01, 1392/09/10
Ethics committee reference number
IR.BUMS.1392.16

Health conditions studied

1

Description of health condition studied
Otomycosis
ICD-10 code
+B36.9
ICD-10 code description
Superficial mycosis, unspecified

Primary outcomes

1

Description
Otomycosis
Timepoint
4, 10, and 10 days after treatment
Method of measurement
Ear examination

Secondary outcomes

empty

Intervention groups

1

Description
The waste mass in the ear canal and also in the presence of pus and fluid in the ear canal will be removed. After removal of the waste, the patient's ear canal will be cleaned with Betadine solution. This work will continue until the ear canal is completely clean
Category
Treatment - Other

2

Description
The waste mass in the ear canal and also in the presence of pus and fluid in the ear canal will be removed. After removal of debris, antifungal drop "clotrimazole" will be administered 3 drops every eight hours, for 4 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza and Valiasr hospitals affiliated to Birjand University of Medical Sciences
Full name of responsible person
MohammadHasan Namaei
Street address
South Khorasan- Birjand- Birjand University of Medical Sciences
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
GholamReza Sharifzade-MSc in Epidemiology-Research Director of University

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Grant name
بودجه های جاری معاونت تحقیقات

Grant code / Reference number
10506

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

Title of funding source
Birjand 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Birjand- Birjand University of Medical Sciences

Full name of responsible person
MohammadReza Mofatteh

Position
Ear, nose and throat specialist-Faculty of Birjand University of Medical Sciences,

Other areas of specialty/work

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Professional medical-doctoral students

Other areas of specialty/work

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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