

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Birjand University of Medical Scie

Country

Iran (Islamic Republic of)

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+98 56 3239 5409

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mhnamaei@bums.ac.ir

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-fungal and corticosteroids 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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South Khorasan- Birjand- Birjand University of Medical Sciences

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Birjand

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**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

Birjand- Birjand University of Medical Sciences

Full name of responsible person

Zahra Naseri Poor Yazdi

Position

Professional medical-doctoral students

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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