

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison of recovery rate of otomycosis using Two treatment tropical Iodine Tincture and tropical clotrimazole

Protocol summary

Summary

This single-blind clinical trial will be performed on 165 patients with confirmed diagnosis of otomycosis who visit the special ENT clinic of Imam Reza affiliated to Birjand University of Medical Sciences during the primary half of 1395 (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 (Iodine Tincture 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: **IRCT2016073020484N4**

Registration date: **2016-08-24, 1395/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Mohammad Hasan Namaei

Name of organization / entity

Birjand University of Medical Scie

Country

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of recovery rate of otomycosis using Two treatment tropical Iodine Tincture and tropical clotrimazole

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: 165

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

Birjand University of Medical Sciences

City

birjand

Postal code**Approval date**

2016-05-23, 1395/03/03

Ethics committee reference number

lr.bums.1395.8

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 Iodine Tincture 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 - Other

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
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

GholamReza Sharifzade-MSc in Epidemiology-
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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****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

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Position

PhD in of Microbiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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

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Full name of responsible person

Mahbube ahi forshe

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