Clinical Trial Protocol
Iranian Registry of Clinical Trials
14 Jan 2022

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

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
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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 ear discharge; a history of ear surgery; a history of anti-fugnal and corticosteroids treatment;
**Health conditions studied**

1. **Description of health condition studied**
   - Otomycosis

2. **ICD-10 code**
   - +B36.9

3. **ICD-10 code description**
   - Superficial mycosis, unspecified

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**Primary outcomes**

1. **Description**
   - Otomycosis

2. **Timepoint**
   - 4, 10, and 10 days after treatment

3. **Method of measurement**
   - Ear examination

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**Secondary outcomes**

empty

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**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

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**Recruitment centers**

1. **Recruitment center**
   - Imam Reza and Valiasr hospitals affiliated to Birjand University of Medical Sciences

   **Full name of responsible person**
   - MohammadHasan Namaei

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**Sponsors / Funding sources**

1. **Sponsor**
   - 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

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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