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: empty
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 Sciences
Country
Iran (Islamic Republic of)
Phone
+98 56 3239 5409
Email address
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 ear discharge; a history of ear surgery; a history of anti-fungal 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**

**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
Street address
South Khorasan- Birjand- Birjand University of Medical Sciences
City
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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact

Person responsible for scientific inquiries
Contact

Postal code
Phone
+98 56 3225 2437
Fax
Email
Drmoffateh@yahoo.com
Web page address
www.bums.ac.ir

Person responsible for updating data
Contact

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