

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Efficacy of clotrimazole 1% cream with miconazole 1% cream in treatment of otomycosis-2014

Protocol summary

Summary

This study was to investigate the therapeutic effect of Miconazole cream 1% and clotrimazole 1% cream in the treatment of the patients who referred to the hospital during the years 2015 to Amir al momenin hospital and diagnosed as otomycosis based on clinical examination. Exclusion criteria included: patient who have otitis externa with canal stenosis; previous ear surgery ; Patients with Diabetes mellitus ; chronic ear discharge and immunodeficiency. patients divided into three groups: A, B and C and basis of the age and sex of the three groups will be matched. Group A(acidified and debridement is used along with a placebo), B (acidified and miconazole cream 1% mobile debridement) ,Group C(acidified and debridement with cream clotrimazole 1%) after a week and then creams will be off under the microscope examination. all patients will be visited at the end of first and second week and re-examination of the ear canal patients with therapeutic response of Good/Moderate response at the fourth week following by microscopic examination for viewing again relapse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502241138N15**

Registration date: **2015-03-26, 1394/01/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of clotrimazole 1% cream with miconazole 1% cream in treatment of otomycosis-2014

Public title

Efficacy of clotrimazole 1 % and miconazole1% in otomycosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: All patients who visit in Amir-Al.. and have a clinical diagnosis for otomycosis. Exclusion: Otitis externa along with external ear canal stenosis;a history of ear surgery; diabetes mellitus; immunocompromise ; chronic discharging ear

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 58

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

GuilanUniversity of Medical Sciences

Street address

Tehran avenue

City

Rasht

Postal code

4139637459

Approval date

2014-12-30, 1393/10/09

Ethics committee reference number

1930459701

Health conditions studied

1

Description of health condition studied

otomycosis

ICD-10 code

H62.2

ICD-10 code description

Otitis externa in mycoses

Primary outcomes

1

Description

Fungal otitis externa

Timepoint

Weekly up to 2 week and at the end of 4th week.

Method of measurement

Clinical examination

Secondary outcomes

1

Description

The patient's response to creams

Timepoint

Weekly up to 2 week and at the end of 4th week.

Method of measurement

Clinical examination

Intervention groups

1

Description

for B acidified and miconazole cream 1% and debridement can be prescribed as creams on the ear by a ENT specialist clinic with the help of a small syringe (2cc) and 18 gauge IV catheter into the external ear canal is infused cream due to the shape of the ear canal and viscosity remains within the canal. this cream will remain for a week inside the ear canal ... after a week and then cream will be off under the microscope examination. then again for another week by the ear canal Same as previous is filled with cream. all patients at the end of the second week and re-examination of the ear canal patients with therapeutic response of Good/Moderate response at the fourth week following by microscopic examination for viewing again relapse.

Category

Treatment - Drugs

2

Description

For Group C acidified and debridement with cream clotrimazole cream 1% is prescribed in the clinic with the help of a small syringe (2cc) and 18 gauge IV catheter into the external ear canal. this cream will remain for a week inside the ear canal ... after a week and then cream will be off under the microscope examination. then again for another week by the ear canal Same as previous is filled with cream. all patients at the end of the second week and re-examination of the ear canal patients with therapeutic response of Good/Moderate response at the fourth week following by microscopic examination for viewing again relapse.

Category

Treatment - Drugs

3

Description

For Group A, acidified and debridement is used along with a placebo .placebo will remain for a week inside the ear canal ... after a week and then placebo will be off under the microscope examination. then again for

another week by the ear canal Same as previous is filled with placebo. all patients at the end of the second week and re-examination of the ear canal patients with therapeutic response of Good/Moderate response at the fourth week following by microscopic examination for viewing again relapse.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralamomenin Hospital

Full name of responsible person**Street address****City**

Rasht

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

Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person

Susan Komaee

Street address

Namjou, Rasht

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Guilan University of Medical Science, Vice Chancellor for Research

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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Hooshang Gerami

Position

Professor

Other areas of specialty/work**Street address**

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

4139637459

Phone

+98 13 3322 5242

Fax**Email**

hg_gerami@yahoo.com

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

Guilan University of Medical Sciences

Full name of responsible person

Dr Hooshang Gerami

Position

Professor

Other areas of specialty/work**Street address**

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

4139637459

Phone

+98 13 3322 5242

Fax**Email**

hg_gerami@yahoo.com

Web page address**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