Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Boric Acid and Polymixin NH on the treament of acute otitis externa

Protocol summary

Summary

.The goal of this study was comparison the effect of Boric acid and Polymixin NH on the treatment of patients with acute external otitis. This is a double blind clinical trial study that was done on patients with acute external otitis who came to ENT clinic.Inclusion criteria: Patients older than 18 years with acute external otitis.Exclusion criteria: Patients that had used systemic or local antibiotics during last two weeks; diabetic paitients; patients with immunosupresive disorders. This study was done on 80 paitients.The paitients were divided in two groups, in the first group ear drop Polymixin NH was prescribed, three drops every eight hours for ten days. In the second group ear drop Boric acid was prescribed, three drops every eight hours for ten days. This study was done between 21/04/2014 and 22/09/2014. primary outcome was pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409256252N6**
Registration date: **2015-05-19, 1394/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-19, 1394/02/29

Registrant information

Name
Soroush Amani
Name of organization / entity
Shahrekord University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 38 1226 4834
Email address
samani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Scienses

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Boric Acid and Polymixin NH on the treament of acute otitis externa

Public title

Comparison of the effect of Boric Acid and Polymixin NH on the treament of external otitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients older than 18 years with acute external otitis. Exclusion criteria: Patients that had used systemic or local antibiotics during last two weeks; Diabetic paitients; Patients with immunosupresive disorders.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sharekord University of Medical Sciences

Street address

Kashani Avenue, Shahrekord

City

Shahrekod

Postal code

8815713471

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

1048

Health conditions studied

1

Description of health condition studied

Acute External Otitis

ICD-10 code

H60.3

ICD-10 code description

diffuse infective otitis externa

Primary outcomes

1

Description

earahce

Timepoint

first day, third day, seventh day and tenth day

Method of measurement

MC Gill Pain Questionnaire

Secondary outcomes

1

Description

discharge from ear

Timepoint

first day, third day, seventh day and tenth day

Method of measurement

clinical evaluation

2

Description

swelling of ear canal

Timepoint

first day, third day, seventh day and tenth day

Method of measurement

clinical evaluation

3

Description

tenderness of auricle

Timepoint

first day, third day, seventh day and tenth day

Method of measurement

clinical evaluation

Intervention groups

1

Description

In the first group ear drop Polymixin NH was prescribed, three drops every eight hours for ten day.

Category

Treatment - Drugs

2

Description

In the second group ear drop Boric acid was prescribed, three drops every eight hours for ten day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatolah Kashani Hospital, Shahrekord

Full name of responsible person

Soroush Amani MD

Street address

Ayatolah Kashani Hospital, Shariati Aveneue,Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Mahmood Mobasheri MD
Street address
Kashani Aveneue, Shahrekord
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord 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
Shahrekord University of Medical Sciences
Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Shahrekord University of Medical Sciences, Kashani Avaneue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 9506
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Shahrekord University of Medical Sciences, Kashani Aveneue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 9506
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Soroush Amani MD
Position
Otolaryngologist
Other areas of specialty/work
Street address
Shahrekord University of Medical Sciences, Kashani Avenue, Shahrekord
City
Shahrekord
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
+98 38 3334 9506
Email
info@Skums.ac.ir
Web page address
http://www.SKUMS.ac.ir

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