

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of the effect of Boric Acid and Polymixin NH on the treatment 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 patients; patients with immunosuppressive disorders. This study was done on 80 patients. The patients 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 Sciences

##### 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 treatment of acute otitis externa

##### Public title

Comparison of the effect of Boric Acid and Polymixin NH on the treatment 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 patients; Patients with immunosuppressive 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 Avenue, 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 Avenue, 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 Avenue, Shahrekord

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**Phone**

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info@Skums.ac.ir

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Other areas of specialty/work**

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## 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**

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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*