

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of prevention of ear canal infection with or without using boric acid and miconazole after suction

Protocol summary

Summary

According to produce of infection in ear canal after removal of cerumen, the aim of this study is prevention or decrease of otitis external and also elimination of additional cost after removal of cerumen. Thus all Patients referred to Rohani Hospital, Babol, Iran, with cerumen in air canal will enter in this study, after Microscopial examination (without any inflammation and infection). All remaining patients will divided to case and control groups as randomized, 100 persons, totally. After suction all plug in air canal (for each group), in case group, they receive boric acid 2% by soab and then Miconazole cream 2%.)we do not use any drugs for control group).All of patients follow for 1 week.

General information

Acronym

prevention of ear infection

IRCT registration information

IRCT registration number: **IRCT201104176208N1**

Registration date: **2011-11-04, 1390/08/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-04, 1390/08/13

Registrant information

Name

Keyvan Kiakojori

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prevention of ear canal infection with or without using boric acid and miconazole after suction

Public title

The effect of boric acid and miconazole in prevention of ear infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All persons with cerumen in air canal

Exclusion criteria: Pain; Inflammation; Bacterial and

Fungal infections; Systemic infection; Media chronic otitis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Ganj Afroos St.

City

Babol

Postal code

4717647745

Approval date

2011-02-28, 1389/12/09

Ethics committee reference number

3150/30/پ/ز

Health conditions studied

1

Description of health condition studied

Pateints with abnormality in hearing, and to need washing

ICD-10 code

H60

ICD-10 code description

Otitis externa

Primary outcomes

1

Description

Prevention of infflamation and pain in air canal

Timepoint

24 hrs and after 1 week

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Pateint satisfaction from hearing

Timepoint

After 1 week

Method of measurement

Clinical examination

Intervention groups

1

Description

Case group: After suction all plug in air canal under microscopical guides, they will receive boric acid 2% by soab and then Miconazole cream 2%. They follow for 1 week. We propose they use boric acid 2% after each bath and without any use soab and prevention of water entry.

Category

Prevention

2

Description

Control group: After suction all plug in air canal under microscopical guides, we do not use any drugs. They follow for 1 week. We propose they use boric acid 2% after each bath and without any use soab and prevention of water entry.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aytollah Roohani Hospital, Babol

Full name of responsible person

Dr. Keyvan Kiakojori

Street address

Aytollah Rohani Hospital,Ganj Afrooz St., Babol

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Ganj Afroos St., Babol

City

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Grant name

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

Yes

Title of funding source

Babol 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**

Babol Univerity Of Medical Sciences

Full name of responsible person

Dr. Keyvan Kiakojoori

Position

Associated Professor

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

Babol University of Medical Sciences

Full name of responsible person

Dr. Keyvan Kiakojoori and Dr. Saeid Mahdavi Omran

Position

Associated Profesor and Assistant Professor,

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Web page address**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*