

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of watchful waiting strategy in the treatment of acute otitis media in children 6 month to 18 years of age

Protocol summary

Study aim

The aim of this study is to evaluate watchful waiting strategy in acute otitis media in children 6 month to 18 years of age.

Design

sampling method was simple and referral base. Information was recorded. Follow-up steps were directly taken by the doctor using examination and telephone conversation. For waiting groups, they were warned that no antibiotics should be given to the child. In case of persistence or worsening the symptoms, they should be referred within 48-72 hours after the onset of rapid symptoms for reassessment and the initiation of antibiotics. Alternatively, in case of no referral or contact with the researcher, the researcher asked the child's situation by telephone with the parents.

Settings and conduct

non-randomized clinical trial in Shiraz ,Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria:children aged between 6 months and 18 years, the presence of mild to moderate AOM, fever less than 39 ° C. Exclusion criteria include recent antibiotic use, facial or cranial deformities, immunodeficiency, malnutrition, frequent history of AOM, history of hearing problems, tympanic membrane perforation, Down syndrome, severe AOM, otorrhea, and poor compliance.

Intervention groups

Watchful waiting group .All of children put on(Watchful waiting) are monitored for up to 72 hours if there was no proper response take antibiotics if needed. Then compare children who recover without antibiotics with those we have to use.

Main outcome variables

Improving the clinical symptoms (descriptive and examination) including pain and fever and relieving inflammation of the eardrum

General information

Reason for update

Acronym

child otitis media study(COMS)

IRCT registration information

IRCT registration number: **IRCT20200610047724N1**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **retrospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Mahnaz Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 2787

Email address

haghighi0005@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2020-02-20, 1398/12/01

Trial completion date

2020-02-20, 1398/12/01

Scientific title

Evaluation of watchful waiting strategy in the treatment of acute otitis media in children 6 month to 18 years of age

Public title

Evaluation of watchful waiting strategy in children with acute otitis media

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children aged between 6 months and 18 years, the presence of mild to moderate AOM, fever less than 39 °C, no toxicity or pussy discharge from the ears physical exam suggestive for AOM (acute otitis media)

Exclusion criteria:

recent antibiotic use facial or cranial deformities immunodeficiency, malnutrition, HIV history of hearing problems, tympanic membrane perforation frequent history of AOM Down syndrome poor compliance

Age

From **6 months** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

The watchful waiting intervention in our study is non-pharmacological. Patients do not have a control group. All patients put on watchful waiting strategy at first except in critical cases. Within 72 hours, those patients who do not respond properly will receive antibiotics.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Islamic Azad University Kazeroon Branch

Street address

Shiraz, No.4, Mollasadra Street, Mollasadra medical center, 3Floor

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Approval date

2020-06-11, 1399/03/22

Ethics committee reference number

IR.IAU.KAU.REC.1399.014

Health conditions studied

1

Description of health condition studied

Acute otitis media

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of children recovering without antibiotics

Timepoint

72 hours , a week and two weeks after treatment

Method of measurement

Improving the patient's symptoms, including fever and otoscopic ear examinations

Secondary outcomes

1

Description

Clinical improvement, elimination of ear pain, restlessness, anorexia, general well-being and elimination of inflammation of the eardrum in the examination

Timepoint

First visit ,48 to 72 hours later, One to two weeks after the first visit

Method of measurement

Ear examination and current present illness

Intervention groups

1

Description

All patients enrolled to the study with a diagnosis of middle ear infection, if they do not meet the conditions for immediate and emergency antibiotic administration, the treatment decision will be based on watchful waiting ,that means the child will be monitored up to 72 hours without antibiotics prescription (only simple analgesics such as acetaminophen if necessary). Antibiotics are

prescribed if warning signs such as worsening of the patient's general symptoms, uncontrollable fever, vomiting, lethargy and intolerance to food are detected within 72 hours. During this period, we monitor the child's symptoms through face-to-face or telephone examination and observation of symptoms and signs .The group has been treated without treatment only under supervision will be the watchful waiting group and those who have not responded in this way and we have to prescribe antibiotics will be in the antibiotic group. Then both groups will be compared in terms of different variables such as sex ,age, post nasal discharge ,adenoid hypertrophy unilateral or bilateral ears involvement and history of atopic conditions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office

Full name of responsible person

Dr Mahnaz Haghighi

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No4.allay ,Mollasadra street ,Mulla Sadra Medical Building, third floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mohammad Hosain Marhamatzade

Street address

5 km of Kazerun-Bushehr road, mailbox168/73135

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahnaz Haghighi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahnaz Haghighi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic Information of Patients, Clinical Symptoms and signs, therapeutic approach including Watchful and waiting versus antibiotic therapy will be available

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

All academic and non-academic researchers

Under which criteria data/document could be used

In order to design and perform similar interventions at a larger size, access to data and applied analysis is possible.

From where data/document is obtainable

Personal email, mobile number and work phone number of researcher.

What processes are involved for a request to access data/document

Documents will be sent within 4 to 8 weeks after the application

Comments

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahnaz Haghighi

Position

Assistant professor

Latest degree

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