

# 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

#### City

Shiraz

#### Province

Fars

#### Postal code

7193615411

#### 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

###### Street address

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

###### City

Shiraz

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###### Postal code

71936-15411

###### Phone

+98 71 3647 2787

###### Email

haghighi0005@gmail.com

### 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

###### City

Kazeroun

###### Province

Fars

###### Postal code

7319846451

###### Phone

+98 71 4223 9933

###### Fax

+98 71 4223 0508

###### Email

drmarhamati@gmail.com

#### Web page address

https://www.kau.ac.ir/%D9%85%D8%AF%DB%8C%D8%B1%DB%8C%D8%AA/%D8%AD%D9%88%D8%B2%D9%87-%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%A A-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C/%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%AA-%D9%BE%DA%98%D9%88%D9%87%D8%B4%DB%8C

#### 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

##### Street address

No.4 , Mollasadra street , Mollasadra medical center , 3Floor

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##### Email

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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

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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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