

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Clinical trial of the effectiveness of comparing the treatment of acute otitis media with Amoxicillin and watchful waiting in 6 months to 6 years old children

#### Protocol summary

##### Study aim

Determining the effect of Amoxicillin and watchful waiting in 6 months to 6 years old children

##### Design

Clinical trial with control group, with parallel groups, simple blind and simple randomization. The sample size is estimated 200 people in each group.

##### Settings and conduct

In this clinical trial 6 months to 6 years old children referring to Infectious diseases clinic of Bouali hospital of Sari were evaluated prospectively. Only data analyser was blinded

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 6 months to 6 years, Acute otitis media with signs started within 48 hours, Not having severe symptoms and ear otorrhea, Unilateral or bilateral involvement Exclusion criteria: Severe otalgia, Fever higher than 39 oc, Underlying diseases such as immunodeficiency, Amoxicillin intake in the last 30 days, Concurrent conjunctivitis, Ear otorrhea

##### Intervention groups

For the intervention group, 80 mg/kg/day, Amoxicillin Suspension, made by Farabi Company with brand name of "Faramox BD" or Amoxicillin-Clavulanate Suspension made by the same Company with brand name of Pharmentin BD, with the same dose in children who receive Amoxicillin one month ago was used for 7 to 10 days, and the control group was followed and monitored without antibiotic treatment and symptoms were evaluated.

##### Main outcome variables

Fever, otalgia, mastoiditis and otorrhea were evaluated at first and third day following treatment. Middle ear effusion and frequency of acute otitis media were evaluated in one and three months after treatment. Any adverse drug reactions including diarrhea, vomiting and allergic reactions were also recorded on the checklist.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111224008507N2**

Registration date: **2018-07-09, 1397/04/18**

Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

##### Registration date

2018-07-09, 1397/04/18

##### Registrant information

##### Name

Mohammad Sadegh Rezai

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 2334

##### Email address

rezai@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2018-06-21, 1397/03/31

##### Actual recruitment start date

2017-08-23, 1396/06/01

##### Actual recruitment end date

2018-06-21, 1397/03/31

##### Trial completion date

empty

### Scientific title

Clinical trial of the effectiveness of comparing the treatment of acute otitis media with Amoxicillin and watchful waiting in 6 months to 6 years old children

### Public title

Comparing the treatment of acute otitis media with Amoxicillin and watchful waiting in 6 months to 6 years old children

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 6 months to 6 years Acute otitis media with signs started within 48 hours Not having severe symptoms and ear otorrhea Unilateral or bilateral involvement

#### Exclusion criteria:

Severe otalgia Fever higher than 39 degrees Underlying diseases such as immunodeficiency (except asthma and allergy) Amoxicillin intake in the last 30 days Concurrent conjunctivitis Ear otorrhea

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **200**

Actual sample size reached: **375**

### Randomization (investigator's opinion)

Randomized

### Randomization description

After obtaining informed consent for randomization form parents of children, patients were placed in intervention (amoxicillin) and control group (watchful waiting) by entering in blocks of four and randomized division

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Data analyser was blinded

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

#### Street address

Vice chancellor for Research, Moallem square, Sari

#### City

Sari

#### Province

Mazandaran

#### Postal code

47128-55689

#### Approval date

2017-08-01, 1396/05/10

#### Ethics committee reference number

IR.MAZUMS.REC.1395.2489

## Health conditions studied

### 1

#### Description of health condition studied

Otitis media

#### ICD-10 code

H65.1

#### ICD-10 code description

Other acute nonsuppurative otitis media

## Primary outcomes

### 1

#### Description

fever

#### Timepoint

At the beginning of the study (before the intervention), three days after treatment

#### Method of measurement

Thermometer

### 2

#### Description

Otalgia

#### Timepoint

At the beginning of the study (before the intervention), three days after treatment

#### Method of measurement

Observation

### 3

#### Description

Mastoiditis

#### Timepoint

At the beginning of the study (before the intervention), three days after treatment

#### Method of measurement

Examination

### 4

#### Description

Middle ear effusion

### **Timepoint**

At the beginning of the study (before the intervention), three days after treatment

### **Method of measurement**

Examination

## **Secondary outcomes**

### **1**

#### **Description**

Frequency of acute otitis media

#### **Timepoint**

One and three months after treatment

#### **Method of measurement**

Observation

### **2**

#### **Description**

Middle ear effusion

#### **Timepoint**

One and three months after treatment

#### **Method of measurement**

Examination

## **Intervention groups**

### **1**

#### **Description**

Intervention group: For the intervention group, 80 mg/kg/day Amoxicillin suspension manufactured by Farabi co. with brand name of Faramox BD will be given for at least 7 days.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: The control group is followed up without antibiotic therapy and with monitoring and evaluation of symptoms. In this group, only patients who are allowed not to use antibiotic treatment and can be expected with care are enrolled under AOM's guideline.

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Bouali Hospital

##### **Full name of responsible person**

Mohammadsadegh Rezai

##### **Street address**

Bouali Hospital, Pasdaran boulevard, Sari

##### **City**

Sari

### **Province**

Mazandaran

### **Postal code**

47128-55689

### **Phone**

+98 11 3334 2334

### **Email**

rezai@mazums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Majid Saidi

##### **Street address**

Vice chancellor for Research, Moallem square, Sari

##### **City**

Sari

##### **Province**

Mazandaran

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##### **Phone**

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##### **Email**

msaidi@mazums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Sari University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **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**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Ensieh Talaei

##### **Position**

Pediatrics' resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Pediatrics

**Street address**

Bouali Hospital, Pasdaran boulevard, Sari

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammadsadegh Rezai

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ensieh Talaei

**Position**

Pediatric Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

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**City**

Sari

**Province**

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**Postal code**

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**Phone**

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**Email**

nctalaie@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data is available

**When the data will become available and for how long**

En starting in January 2020

**To whom data/document is available**

All people

**Under which criteria data/document could be used**

Nothing

**From where data/document is obtainable**

Contact Dr. Ensieh Talaei. E-mail: nctalaie@gmail.com

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

After a call, information is sent within a few days

**Comments**