

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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	Ethics committee of Mazandaran University of Medical Sciences
Scientific title	Street address
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	Vice chancellor for Research, Moallem square, Sari
Public title	City
Comparing the treatment of acute otitis media with Amoxicillin and watchful waiting in 6 months to 6 years old children	Sari
Purpose	Province
Treatment	Mazandaran
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	47128-55689
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	Approval date
Exclusion criteria:	2017-08-01, 1396/05/10
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	Ethics committee reference number
Age	IR.MAZUMS.REC.1395.2489
From 6 months old to 6 years old	Health conditions studied
Gender	1
Both	Description of health condition studied
Phase	Otitis media
3	ICD-10 code
Groups that have been masked	H65.1
• Data analyser	ICD-10 code description
Sample size	Other acute nonsuppurative otitis media
Target sample size: 200	Primary outcomes
Actual sample size reached: 375	1
Randomization (investigator's opinion)	Description
Randomized	fever
Randomization description	Timepoint
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	At the beginning of the study (before the intervention), three days after treatment
Blinding (investigator's opinion)	Method of measurement
Single blinded	Thermometer
Blinding description	2
Data analyser was blinded	Description
Placebo	Otalgia
Not used	Timepoint
Assignment	At the beginning of the study (before the intervention), three days after treatment
Parallel	Method of measurement
Other design features	Observation
Secondary Ids	3
empty	Description
Ethics committees	Mastoiditis
1	Timepoint
Ethics committee	At the beginning of the study (before the intervention), three days after treatment
Name of ethics committee	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

Postal code

47128-55689

Phone

+98 11 3334 2334

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

City

Sari

Province

Mazandaran

Postal code

47128-55689

Phone

+98 11 3334 2334

Email

nasimmeh62@yahoo.com

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

Street address

Bouali Hospital, Pasdaran Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

47128-55689

Phone

+98 11 3334 2334

Email

drmsrezaii@yahoo.com

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

Bouali Hospital, Pasdaran Boulevard

City

Sari

Province

Mazandaran

Postal code

47128-55689

Phone

+98 11 3334 2334

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