

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparing synthetic impact of zinc and probiotic with amoxicillin in treatment of acute otitis media in children 6 months-6 years old in children,s Bandar abbas hospital 2018

Protocol summary

Study aim

The comparing synthetic impact of zinc and probiotic with amoxicillin in treatment of acute otitis media in children 6 months-6 years old in children,s Bandar abbas hospital 2018

Design

Clinical trial without blind, randomized, double blind, sample size 94 people,2018

Settings and conduct

randomized clinical trial in Bandar Abbas Children's Hospital

Participants/Inclusion and exclusion criteria

Entry Criteria: 1. Children 6 months to 6 years 2
Diagnosis of acute mediastinal otitis media: history of acute onset of symptoms with fluid in the middle ear and inflammatory symptoms (at least one of the following: 1. earache 2. intense redness of thymipan 3. thymiphanum bulimia) Exit criteria: 1. Receiving Zinc or Probiotic 2. Chronic pulmonary or cardiac disease or immune deficiency (primary or secondary) 3. Sensitivity to zinc or phenylketonuria 4.No cooperation of parents

Intervention groups

Amoxicillin, zinc and probiotics recipients

Main outcome variables

Improvement of symptoms include pain, redness, protuberance, and type A tympanometry

General information

Reason for update

Acronym

AZPO

IRCT registration information

IRCT registration number: **IRCT20180829040901N1**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Maryam Mojdeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 7210

Email address

mohammadbagher.rahmati@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

2018-04-20, 1397/01/31

Scientific title

The comparing synthetic impact of zinc and probiotic with amoxicillin in treatment of acute otitis media in children 6 months-6 years old in children,s Bandar abbas hospital 2018

Public title

Effects of Amoxicillin, Zinc and Probiotics on Mid-Ear Infection(AOM)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6 months to 6 years old
Diagnosis of acute mediastinal otitis media: history of acute onset of symptoms with fluid in the middle ear and inflammatory symptoms (at least one of the following: 1. earache 2. intense redness of tympan 3. tympan bulimia)

Exclusion criteria:

Getting Zinc or Probiotic
Chronic pulmonary or cardiac disease or immune deficiency (primary or secondary)
Sensitization to zinc or phenylketonuria
Lack of parental cooperation

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **126**

Actual sample size reached: **94**

Randomization (investigator's opinion)

N/A

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

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Bandar Abbas Children's Hospital, Daropakshh St., Northern Golshahr St.

City

Bandar abbas

Province

Hormozgan

Postal code

7915873665

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.HUMS.REC.1397.020

Health conditions studied

1

Description of health condition studied

Acute Otitis Media

ICD-10 code

H65.0

ICD-10 code description

Acute serous otitis media

Primary outcomes

1

Description

Otitis media treatment with three drug groups

Timepoint

At the time of referral, the diagnosis of otitis media, the initiation of treatment, and then 10 days of treatment, and then the effect of treatment by examination and tympanometry

Method of measurement

Clinical examination and otoscope and tympanometry

Secondary outcomes

empty

Intervention groups

1

Description

Group one: Amoxicillin from the Farabi Pharmaceutical Company at a dose of 90-80 mg per kg daily for 10 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: Zinc from Razi Pharmaceuticals received 10 mg of lentil with amoxicillin from the Farabi Pharmaceutical Company at a dose of 90-80 mg per kg of weight for ten days.

Category

Treatment - Drugs

3

Description

Intervention group 3: Probiotics (from the Nikotech Pharmaceuticals Company) receive a saccharide with amoxicillin from Farabi Pharmaceuticals at a dose of 90-80 mg per kilogram for ten days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Children's Hospital

Full name of responsible person

Maryam Mojdeh

Street address

Bandar Abbas Children's Hospital, Daropakhsh St.,Northern Golshahr St.

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maryam_mojdeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Farideh Hasan zadeh

Street address

Bandar Abbas Children's Hospital, Daropakhsh Avenue,Northern Golshahr Ave.

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Grant name

-

Grant code / Reference number

-

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

No

Title of funding source

-

Proportion provided by this source

1

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Mojdeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mohammad Bagher Rahmati

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Mojdeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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

The total potential data can be shared after being unidentified.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Any analysis on the delivered data is allowed.

From where data/document is obtainable

mbrahimati@yahoo.com 00989177615397 Dr. mohammad bagher rahmati

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

Time to access file and documentation for about a year

Comments