

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparison of efficacy and safety of Azithromycin and Amoxicillin-Clavulante in the treatment of acute bacterial sinusitis in adults.

#### Protocol summary

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##### Summary

This was a single blind clinical trial on 78 patients with acute bacterial sinusitis. Because of continues changing in bacterial resistance to drugs these studie are necessary. This study has done to compare the effect of Azithromycin and Amoxicillin-Clavulanate on treatment of acute bacterial sinusitis. Inclusion criterias were at least two major or one major and two minor criterias for diagnosis of acute bacterial sinusitis. Exclusion criterias were: choronic sinusitis; recurrent sinusitis; drugs consumption and... . One group was administered Azithromycin 500mg daily for three days and another group was administered Amoxicillin-Clavulanate 625 mg three times daily for ten days.

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2013-04-04, 1392/01/15

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201401046252N5**

Registration date: **2014-02-11, 1392/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-11, 1392/11/22

##### Registrant information

###### Name

Soroush Amani

###### Name of organization / entity

Shahrekord University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 1226 4834

###### Email address

##### Scientific title

A comparison of efficacy and safety of Azithromycin and Amoxicillin-Clavulante in the treatment of acute bacterial sinusitis in adults.

##### Public title

Comparison effect of Azithromycin and Amoxiclave in treatment of acute sinusitis.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Having at least two major or one major and two minor sinusitis criterias that have lasted 7 to 28 days. Major criterias included: pain or feeling of fullness in face; nasal obstruction; nasal or postnasal discharge; anosmia or hyposmia; fever. Minor criterias included: headache; halitosis; fatigue; toothache; cough; otalgia or feeling of fullness in the ears. Exclusion criterias: choronic sinusitis; recurrent sinusitis; anatomic deformitis (severe septal deviation; cleft palate); choronic disease (hepatic; renal; cardiac and ashtma); pregnancy and breast feeding; allergy to drugs; ciliary dysfunction; cystic fibrosis; HIV infection; diabetes; using of steroid; complication of sinusitis like orbital cellulitis; using of

antibiotics in last 30 days; having less than 12 years old or more than 65 years old.

#### Age

From **12 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **78**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahrekord University of Medical Sciences

##### Street address

Kashani Avenue, Shahrekord

##### City

Shahrekord

##### Postal code

8815713471

#### Approval date

2013-09-15, 1392/06/24

#### Ethics committee reference number

1392-6-24

## Health conditions studied

### 1

#### Description of health condition studied

Sinusitis

#### ICD-10 code

J01.9

#### ICD-10 code description

Diseases of respiratory system

## Primary outcomes

### 1

#### Description

Facial pain

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 2

#### Description

Nasal obstruction

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 3

#### Description

Nasal or postnasal discharge

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 4

#### Description

Anosmia or hyposmia

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 5

#### Description

Fever

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

With thermometer

## Secondary outcomes

### 1

#### Description

Headache

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 2

#### Description

Halitosis

#### Timepoint

First day- fifth day- tenth day

#### Method of measurement

Visual

### 3

**Description**

Fatigue

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

### 4

**Description**

Toothache

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

### 5

**Description**

Cough

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

### 6

**Description**

Otalgia or feeling of fullness in ears

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

### 7

**Description**

Diarrhea

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

### 8

**Description**

Vomiting

**Timepoint**

First day- fifth day- tenth day

**Method of measurement**

Visual

## Intervention groups

### 1

**Description**

In first group Azithromycin was administered 500mg daily for three days.

## Category

Treatment - Drugs

### 2

**Description**

In second group Amoxicillin-Clavulante was administered 625mg three times daily for ten days.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahrekord kashani hospital

**Full name of responsible person**

Soroush Amani MD

**Street address**

Kashani hospital, Shariati Avenue, Shahrekord

**City**

Shahrekord

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Dr Mahmood Mobashery

**Street address**

Shahrekord University of Medical Sciences, Kashani Avenue, Shahrekord

**City**

Shahrekord

**Grant name**

ندارد

**Grant code / Reference number**

Do not have

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

Yes

**Title of funding source**

Shahrekord University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Soroush Amani MD

**Position**

Otolaryngologist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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**Postal code**

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**Phone**

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**Fax**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*