

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect and side effects of Azitromycin and co-Amoxiclav in the treatment of acute bacterial sinusitis in adults.

#### Protocol summary

##### Summary

The aim of this study is the comparison effect of Azitromycin and Co\_amoxiclav on acute sinusitis in adults. This study is a double blind clinical trial. the population have studied are patients with acute sinusitis and between 12-65 years old. Inclusion criteria: Existing at least two major criteria or one major criteria and two minor criteria. Major criteria are: facial pain; nasal obstruction and.... Minor criteria: headache; halitosis and... . Exclusion criteria: Patients with chronic sinusitis; patients with recurrent sinusitis; patients with anatomical disorders (severe septal deviation; cleft palate; nasal poliposis) and... .Sample size are 90. The patients are divided in two groups: First group are prescribed one tablet Azitromycin 500 mg daily for three days, second group are prescribed Co\_amoxiclav capsule 625 mg every 8 hours for 10 days. This study has done in the spring and summer of the 2013. In the end of the study, the patients with no evidence of acute sinusitis criteria considered cured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201505106252N7**

Registration date: **2015-06-02, 1394/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-02, 1394/03/12

##### 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

samani@skums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Shahrekord University of Medical Sciences

###### Expected recruitment start date

2014-04-21, 1393/02/01

###### Expected recruitment end date

2015-02-19, 1393/11/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of the effect and side effects of Azitromycin and co- Amoxiclav in the treatment of acute bacterial sinusitis in adults.

###### Public title

Comparison of the effect of Azitromycin and co-Amoxiclav in the treatment of adult sinusitis.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Existing at least two major criteria or one major criteria and two minor criteria that lasting at least 7 days and at most 28 days. Major criteria are: facial pain or pressure; facial fullness or congestion; nasal obstruction; purulent rhinorrhea or postnasal discharge; loss of smell; fever. Minor criteria: headache; halitosis; fatigue; toothache; cough; otalgia; fullness of

ear. Exclusion criteria: Patients with chronic sinusitis; patients with recurrent sinusitis; patients with anatomical disorders( severe septal deviation; cleft palate; nasal poliposis; patients with chronic disorders (severe hepatic disease; renal disease; heart disease and asthma); women in pregnancy and breast feeding; history of sensitivity to co\_ amoxiclav or azitromycin; patients with cilliary dysfunction; cystic fibrosis; congenital or acquired immune deficiency (HIV; diabetes); complications of sinusitis; antibiotic consumption in last one month; patients 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: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Sharekord University of Medical Sciences

**Street address**

Kashani Avenue, Shahrekord

**City**

Shahrekod

**Postal code**

8815713471

**Approval date**

2013-10-12, 1392/07/20

**Ethics committee reference number**

24-6-92

**Health conditions studied****1****Description of health condition studied**

Acute sinusitis

**ICD-10 code**

J01.9

**ICD-10 code description**

Acute sinusitis, unspecified

**Primary outcomes****1****Description**

Facial pain

**Timepoint**

fifth day, tenth day

**Method of measurement**

clinical evaluation

**2****Description**

Feeling of fullness or congestion of the face

**Timepoint**

fifth day, tenth day

**Method of measurement**

clinical evaluation

**3****Description**

Nasal obstruction

**Timepoint**

fifth day, tenth day

**Method of measurement**

clinical evaluation

**4****Description**

Purulent discharge of nose or postnasal discharge

**Timepoint**

fifth day, tenth day

**Method of measurement**

clinical evaluation

**5****Description**

Loss of smell

**Timepoint**

fifth day, tenth day

**Method of measurement**

clinical evaluation

**6****Description**

Fever

**Timepoint**

fifth day, tenth day

**Method of measurement**

cheking with termometer

## Secondary outcomes

### 1

**Description**

Headache

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

### 2

**Description**

Hallitosis

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

### 3

**Description**

Fatigue

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

### 4

**Description**

Toothache

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

### 5

**Description**

Cough

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

### 6

**Description**

Otalgia or feeling of fullness in the ear

**Timepoint**

fifth day, tenth day

**Method of measurement**

history

## Intervention groups

### 1

**Description**

In the first group Azitromycin 500 mg tablet was prescribed daily for three days.

**Category**

Treatment - Drugs

### 2

**Description**

In the second group Co-Amoxiclav 625 capsule was prescribed every eight hours for ten days.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Soroush Amani MD

**Street address**

Shariati Avenue, Shahrekord

**City**

Shahrekord

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Mahmood Mobasheri MD

**Street address**

Kashani Avenue, Shahrekord

**City**

Shahrekord

**Grant name****Grant code / Reference number****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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**Full name of responsible person**

Soroush Amani MD

**Position**

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<http://www.SKUMS.ac.ir>

**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*