Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

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

Protocol summary

Summary

This was a single blind clinical trial on 78 patients with acute bacterial sinusitis.Beacause of continues changing in bacterial resistance to drugs these studise 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 Azithromycin500mg daily for three days and another group was administered Amoxicillin-Clavulanate 625 mg three times daily for ten days.

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

samani@skums.ac.ir

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

Scientific title

A comparsion of efficacy and safety of Azithromycin and Amoxicillin-Clavulante in the treatement 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 7to28days. 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; cilliary dysfunction; cystic fibrosis; HIV infection; diabetes; using of steroid; complication of sinusitis like orbital cellulitis; using of

antibiotics in last 30 days; having less12 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
JO1.9

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 termometer

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 Aveni ue,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 Unhversity of Medical Sciences

Full name of responsible person
Soroush Amani MD

Position
Otolaryngologist

Other areas of specialty/work

Street address
Shahrekord University of Medical Sciences,Kashani Avenue,Shahrekord

City
Shahrekord

Postal code
8815713471

Phone
+98 38 1333 0061

Fax
+98 38 1334 3004

Email
info@Skums.ac.ir

Web page address
http://www.SKUMS.ac.ir

Person responsible for scientific 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
Shahrekord University of Medical Sciences,Kashani Avenue,Shahrekord

City
Shahrekord

Postal code
8815713471

Phone
+98 38 1333 0061

Fax
+98 38 1334 3004

Email
info@Skums.ac.ir

Web page address
http://www.SKUMS.ac.ir

Person responsible for updating data

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
Shahrekord University of Medical Sciences,Kashani Avenue,Shahrekord

City
Shahrekord

Postal code
8815713471

Phone
+98 38 1333 0061

Fax
+98 38 1334 3004

Email
info@Skums.ac.ir

Web page address
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