Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of Cefixime and Cefixime and Clindamycin Combination with Cefixime in the Treatment of Acute and Chronic Sinusitis patients in Imam Khomeini Hospital of Ahwaz

Protocol summary

Study aim
Comparison of cefixime and the combination of cefixime and clindamycin with cefixime in the treatment of acute and chronic sinusitis

Design
This study was a clinical trial with a control group, with parallel, unfocused, and randomized groups, phase 3, which was performed on 120 patients in four groups. For randomization, the Excel function rand function based on the patient file number will be used.

Settings and conduct
The present study will be performed on patients with acute and chronic rhinosinusitis referred to the ENT clinic of Ahvaz Imam Khomeini Hospital in 2021.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Initial positive opinion by an ear, nose and throat specialist based on examination of the patient's sinuses and consent to the study Non-entry conditions: Allergy to cefixime and Clinda mycin antibiotics, recent use of other antibiotics, cystic fibrosis patients, immunodeficiency

Intervention groups
The first group includes patients with acute sinusitis who take cefixime 400 mg daily and clindamycin 300 mg daily. The second group includes patients with acute sinusitis who receive only 400 mg of cefixime daily. The third group includes patients with chronic sinusitis who take cefixime 400 mg daily and clindamycin 300 mg daily. The fourth group includes patients with chronic sinusitis who receive only 400 mg of cefixime daily.

Main outcome variables
Treatment of acute and chronic sinusitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201112049371N1**
Registration date: **2020-12-21, 1399/10/01**
Registration timing: **retrospective**

Last update: **2020-12-21, 1399/10/01**
Update count: **0**

Registration date
2020-12-21, 1399/10/01

Registrant information

Name
Fateme Boveiri konari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3222 2818

Email address
fafa.boveiri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Cefixime and Cefixime and Clindamycin Combination with Cefixime in the Treatment of Acute and

Chronic Sinusitis patients in Imam Khomeini Hospital of Ahwaz

Public title
Comparison of cefixime and the combination of cefixime and clindamycin in the treatment of patients with acute and chronic sinusitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Initial positive opinion by the ENT specialist on CT scan of the patient's sinuses Patient consent to enter the study
Exclusion criteria:
Hypersensitivity to the antibiotic Cefixime Hypersensitivity to the antibiotic clindamycin Recent use of other antibiotics Patients with cystic fibrosis Immune Deficiency Patients
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random function of Excel software based on patient file number will be used for randomization. Patients with acute and chronic sinusitis were included in the Excel program based on the file number. Based on the random button, patients with acute sinusitis were divided into case and control groups, and patients with chronic sinusitis were divided into case and control groups. A total of four groups of 30 people were divided between 4 groups. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 4 groups that can be numbered from 1 to 4, respectively. We also want 30 people in each group. As a result, sequences 1 to 4 should be repeated 10 times each time.It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 30 for repeating the sequence. In this way, 120 units will be produced.
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 Ahvaz University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Esfand St.,Shahr-e-Daneshgahi, Golestan Blvd.,
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2018-05-19, 1397/02/29
Ethics committee reference number
IR.AJUMS.REC.1397.134

Health conditions studied

1

Description of health condition studied
Acute sinusitis
ICD-10 code
J01
ICD-10 code description
Acute sinusitis

2

Description of health condition studied
Chronic sinusitis
ICD-10 code
J32
ICD-10 code description
Chronic sinusitis

Primary outcomes

1

Description
Headache
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect (3 points) or full effect (4 points)

2

Description
Nasal discharge
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect

(3 points) or full effect (4 points)

3

Description
Cough
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect (3 points) or full effect (4 points)

4

Description
Nasal obstruction
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect (3 points) or full effect (4 points)

5

Description
Feeling full in the face
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect (3 points) or full effect (4 points)

6

Description
Discharge from the back of the throat
Timepoint
At the beginning of the study and 21 days after the study
Method of measurement
No effect (1 point), partial effect (2 points), partial effect (3 points) or full effect (4 points)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes patients with acute sinusitis who receive cefixime tablets (Kowsar company) 400 mg daily and clindamycin capsules (Saha Daroo company) 300 mg three times a day for 21 days.
Category
Treatment - Drugs

2

Description
Control group: includes patients with acute sinusitis who receive only 400 mg daily tablets of Cefexime (Kosar Company) for 21 days.
Category
Treatment - Drugs

3

Description
Intervention group: includes patients with chronic sinusitis who receive cefixime tablets (Kosar company) 400 mg daily and clindamycin capsules (Saha Daroo company) 300 mg three times a day for 21 days.
Category
Treatment - Drugs

4

Description
Control group: includes patients with chronic sinusitis who receive only 400 mg daily tablets of Cefexime (Kosar Company) for 21 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Azam Fazlipour
Street address
Ahvaz Jundishapur University of Medical SciencesEsfand St.,Shahr-e-Daneshgahi,Golestan Blvd.,
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https://www.ajums.ac.ir/fa-IR/Portal/1/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Azam Fazlipour
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Ahvaz Jundishapur University of Medical Sciences, Esfand St., Shahr-e-Daneshgahi,, Golestan Blvd.,

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Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Azam Fazlipour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Azam Fazlipour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Azam Fazlipour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable