

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)

Phone

+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

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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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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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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

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Full name of responsible person

Dr Azam Fazlipour

Position

Associate professor

Latest degree

Specialist

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Ear, Nose, and Throat

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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