Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of azithromycin with erythromycin for the treatment of patients with chronic sinusitis

Protocol summary

Study aim
Comparison of the effect of azithromycin with clarithromycin in the treatment of chronic sinusitis

Design
Randomized phase-3 parallel-group trial with blinded outcome assessment on 90 patients, randomization by Random Allocation software

Settings and conduct
Chronic sinusitis patients referred to Shahid Mohammadi Hospital Otolaryngology Clinic, Bandar Abbas in 2018-2019 were randomized into two groups. In addition to specific treatments for each group, both received the following treatments: 1. Nasal irrigation with normal saline 4 times a day followed by 0.1% oxymetazoline spray, two puffs each nostril 4 times a day for 5 days, 2. Fluticasone spray two puffs each nostril 4 times a day for 2 weeks and then twice for 2 weeks followed by steam inhalation for 10 min for a week. 3. Two long-acting betamethasone intramuscular injections 2 weeks apart, 5 ml guaifenesin syrup TID for 10 days, and 120 mg fexofenadine QHS in case of allergic symptoms. LMS score and symptoms were assessed before and after treatment by an individual blinded to the groupings of the patients.

Participants/Inclusion and exclusion criteria
Patients with chronic sinusitis aged 18-65 years, without polyp, mass, or severe nasal deviation upon endoscopy, without antibiotic use in the past 3 months and topical drugs in the past month, without diabetes, hypertension, or cardiovascular diseases, without periodontal infections, non-pregnant and non-lactating, without systemic illnesses involving the sinuses, without evidence of fungal infection, unilateral maxillary sinus involvement or mucous retention cyst in the maxillary sinus in CT scan

Intervention groups
The azithromycin group received 500 mg single-dose azithromycin daily for 4 weeks and the clarithromycin group received 1000 mg of clarithromycin in two 500-mg doses daily for 4 weeks.

Main outcome variables
Sinusitis symptoms, LMS score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201209049661N1**
Registration date: **2021-06-12, 1400/03/22**
Registration timing: **retrospective**

Last update: **2021-06-12, 1400/03/22**
Update count: **0**

Registration date
2021-06-12, 1400/03/22

Registrant information

Name
Mehdi Askari

Name of organization / entity
Hormozgan University of Medical Sciences, Faculty of Medicine

Country
Iran (Islamic Republic of)

Phone
+98 76 3370 0370

Email address
m_askari_2@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-04-20, 1395/02/01

Expected recruitment end date
2017-04-21, 1396/02/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2019-04-21, 1398/02/01

Trial completion date

2019-06-21, 1398/03/31

Scientific title

Comparison of the effect of azithromycin with erythromycin for the treatment of patients with chronic sinusitis

Public title

Azithromycin vs. clarithromycin for the treatment of chronic sinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of chronic sinusitis based on the Rhinosinusitis Task Force (RTF) criteria Confirmation of chronic sinusitis by CT scan 18-65 years of age

Exclusion criteria:

Presence of polyp, mass, or severe nasal septal deviation (requiring surgery or obstructing the sinus ostia) upon endoscopic examination Antibiotic use within the past 3 months Any topical drug (drop or spray) within the past month Sinus or nasal surgery Hypersensitivity to macrolides Pregnancy or lactation Diabetes mellitus Hypertension Cardiovascular diseases Periodontal infection of the tooth roots adjacent to the maxillary sinus Systemic illnesses involving the sinuses including Wegener's granulomatosis, sarcoidosis, malignancies, lymphoma, cystic fibrosis, AIDS, primary ciliary dyskinesia CT scan findings of inhomogeneous densities indicating probable fungal infections, unilateral involvement of the maxillary sinuses, and presence of mucous retention cysts in the maxillary sinus

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **58**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was done using a randomization table generated by the Random Allocation software. The unit of randomization was an individual subject. Sealed envelopes were numbered from 1 to 90 including the group of the patient based on the randomization table. Each envelope was allocated to a patients in order of their entrance to the study from 1 to 90.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person responsible for recording patients' symptoms and outcomes was blinded to the groupings of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Technology and Research Vice-chancellery, East Side of Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2016-04-03, 1395/01/15

Ethics committee reference number

IR.HUMS.REC.1395.76

Health conditions studied

1

Description of health condition studied

Chronic sinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes

1

Description

Improvement of imaging findings

Timepoint

At the end of 4 weeks of treatment

Method of measurement

LMS (Lund-Mackay Staging) score

2

Description

Improvement of sinusitis symptoms

Timepoint
At the end of 4 weeks of treatment
Method of measurement
Patient's history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Azithromycin, received 500 mg single-dose azithromycin (SANA MED pharmaceutical Co., Iran) daily for 4 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Clarithromycin , received 1000 mg of clarithromycin (Tehran Chiemie Pharmaceutical Co., Iran) in two 500-mg doses daily for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Otorhinolaryngology clinic of Bandar Abbas Shahid Mohammadi Hospital
Full name of responsible person
Mehdi Askar
Street address
Otorhinolaryngology clinic of Bandar Abbas Shahid Mohammadi Hospital, Jomhouri Eslami Blvd., Bandar Abbas, Iran
City
Bandar Abbas
Province
Hormozgan
Postal code
7919783141
Phone
+98 76 3334 7000
Fax
+98 76 3334 5003
Email
shmh@hums.ac.ir
Web page address
https://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Technology and Research Vice-chancellery, Hormozgan University of Medical Sciences
Full name of responsible person
Nasrin Davari Dolatabadi
Street address
Technology and Research Vice-chancellery, East Side of Payambar Azam Hospital, Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 76 3333 7379
Email
n.davari@hums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Technology and Research Vice-chancellery, Hormozgan 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mehdi Askar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Faculty of medicine, Imam Hossein Blvd., across from Kargaran Sports Complex, Bandar Abbas, Hormozgane
City
Bandar Abbas
Province
Hormozgan
Postal code

7919693116

Phone
+98 76 3371 0370

Email
m_askari_2@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Mehdi Askari

Position
Assistant professor

Latest degree
Specialist

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

Street address
Faculty of medicine, Imam Hossein Blvd., across from Kargaran Sports Complex, Bandar Abbas, Iran

City
Bandar Abbas

Province
Hormozgan

Postal code
7919693116

Phone
+98 76 3371 0370

Email
m_askari_2@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Mehdi Askari

Position
Assistant professor

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Faculty of medicine, Imam Hossein Blvd., across from Kargaran Sports Complex, Bandar Abbas, Iran

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Province
Hormozgan

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7919693116

Phone
+98 76 3371 0370

Email
m_askari_2@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available