

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

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## Person responsible for updating data

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Bandare-abbas University of Medical Sciences

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Mehdi Askari

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## 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