Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of clarithromycin and doxycycline treatment on sinonasal outcome in patients with chronic rhinosinusitis with polyps after functional endoscopic sinus surgery, a clinical trial study

Protocol summary

Study aim

The effect of clarithromycin and doxycycline treatment on sinonasal outcome in patients with chronic rhinosinusitis with polyps after functional endoscopic sinus surgery, a clinical trial study

Design

A double-blind clinical trial study including placebo on 192 patients with chronic rhinosinusitis who have undergone endoscopic functional sinus surgery before the start of the study and randomly divided into three groups of 64 people using sealed envelope software. The execution and production of the randomization sequence will be done by a researcher who is not involved in the clinical stages of the project, so that both the patient and the researcher are blinded.

Settings and conduct

Location: Amir Al Mo'menin Hospital (Rasht, Iran); Patients and researchers are blinded and samples are randomly selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participation, 18 - 65 years, Disease diagnosis based on clinical symptoms and CT scan by an ENT surgeon, Presence of sinus polyps with no clinical response to antibiotic treatments, Lund Mackay score of 20 or above, Normal coagulation tests History of endoscopic nasal surgery. Non-inclusion criteria: History of systemic diseases involving the nose and sinuses, Fungal sinusitis, Allergy to macrolides or tetracyclines, Pregnancy and breastfeeding, History of coagulation disease or the use of anticoagulants, Severe systemic diseases, Mucocele, Surgery complications, Taking medications with drug interactions with the antibiotics using in this study

Intervention groups

Group Doxycycline + placebo (Patients receiving Doxycycline as add-on therapy); Group Clarithromycin + placebo (Patients receiving Clarithromycin as add-on therapy); Group placebo + placebo (Patients receiving CRS standard regimen)

Main outcome variables

Recurrence of disease and Sinonasal outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056910N1**
Registration date: **2023-01-03, 1401/10/13**
Registration timing: **prospective**

Last update: **2023-01-03, 1401/10/13**
Update count: **0**

Registration date

2023-01-03, 1401/10/13

Registrant information

Name

Enayatalah gholamalian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3234 7870

Email address

ghbasim@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of clarithromycin and doxycycline treatment on sinonasal outcome in patients with chronic rhinosinusitis with polyps after functional endoscopic sinus surgery, a clinical trial study

Public title

The effect of clarithromycin and doxycycline treatment on chronic rhinosinusitis with polyps after functional endoscopic sinus surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Age 18 - 65 years Disease diagnosis based on clinical symptoms and computerized tomography scan (CT scan) by an Otorhinolaryngology surgeon Presence of sinus polyps with no clinical response to antibiotic treatments Patients with a Lund Mackay score of 20 or above Normal coagulation tests including prothrombin time (PT) , partial thromboplastin time (PTT), international normalized ratio (INR) History of endoscopic nasal surgery before the study

Exclusion criteria:

History of systemic diseases involving the nose and sinuses such as Wegener's disease, sarcoidosis, cicatricial pemphigoid, acquired immunodeficiency syndrome (AIDS) , T-cell lymphoma, primary ciliary dyskinesia, cystic fibrosis, tumors of the nose and sinuses Fungal sinusitis History of allergy to macrolides or tetracyclines Pregnancy and breastfeeding in women History of coagulation disease (such as hemophilia) or the use of anticoagulants such as heparin Severe systemic diseases such as uncontrolled diabetes or severe congestive heart failure Mucocele Surgery complications Taking medications with drug interactions with the antibiotics using in this study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients would be divided into three groups by Block Randomization and using PASS 11.0 software. The execution and production of the randomization sequence will be done by a researcher who is not involved in the clinical stages of the project, and the assistants of the project will register the participants and assign them to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to avoid bias and increase validity, the double-blind method will be used in this research: the patients (through placebo) and the researcher (blind to the sample allocation and prescription drugs) have been blinded; the patients have been divided into three groups of 64 by the sealed envelope software and each patient will receive his own three-digit code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committees of Guilan University of Medical science

Street address

Guilan university of medical science

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2022-08-31, 1401/06/09

Ethics committee reference number

IR.GUMS.REC.1401.301

Health conditions studied

1

Description of health condition studied

Chronic Rhinosinusitis - Nasal Polyps

ICD-10 code

J32-J33

ICD-10 code description

Chronic Sinusitis – Nasal polyp

Primary outcomes

1

Description

Recurrence of disease

Timepoint
First, third, and sixth months follow up
Method of measurement
Based on physical examination and endoscopic findings

2

Description
Sinonasal outcome
Timepoint
First, third, and sixth months follow up
Method of measurement
Based on sino-nasal outcome test 22 score (SNOT-22 score)

Secondary outcomes

1

Description
Endoscopic condition
Timepoint
First, third,and sixth months follow up
Method of measurement
Lund-Kennedy scale

2

Description
Drugs adverse effects
Timepoint
First, third, sixth months follow up
Method of measurement
Clinical history and physical examination

Intervention groups

1

Description
Doxycycline + placebo group: patients receiving Doxycycline as add-on therapy to standard chronic rhinosinusitis (CRS) treatment : After endoscopic functional sinus surgery, 64 patients assigned to this group were treated for at least three weeks with Doxycycline 100 mg capsules and placebo tablets along with the standard chronic rhinosinusitis regimen (nasal irrigation with physiological serum, fluticasone steroid spray two puffs in the morning and night). The failure or success of treatment will be evaluated through clear reduction of signs and symptoms, improvement of quality of life and prevention of progression or recurrence of the disease based on endoscopic findings and by continuous follow-up. All patients refer to Amir al-Momenin Hospital on an outpatient basis at the same and specified time intervals for clinical re-evaluation and sinus endoscopy. In these consultations, which take place one month, three months and six months after surgery, all patients are evaluated with SNOT22 and Lund Kennedy questionnaires, and the patients' information is recorded. In other words, the follow-up period of patients will be 6 months. Also, patients will be checked for drug side effects after starting the treatment. The evaluated side effects of Doxycycline include increased blood pressure, diarrhea, abdominal pain, back pain, hyperpigmentation of the skin, and inflammation and ulceration of the esophagus.
Category
Treatment - Drugs

2

Description
Clarithromycin + placebo group: patients receiving Clarithromycin as add-on therapy to standard chronic rhinosinusitis (CRS) treatment : After endoscopic functional sinus surgery, 64 patients assigned to this group were treated for at least three weeks with Clarithromycin 500 tablets and placebo capsules along with the standard chronic rhinosinusitis regimen (nasal irrigation with physiological serum, fluticasone steroid spray two puffs in the morning and night). The failure or success of treatment will be evaluated through clear reduction of signs and symptoms, improvement of quality of life and prevention of progression or recurrence of the disease based on endoscopic findings and by continuous follow-up. All patients refer to Amir al-Momenin Hospital on an outpatient basis at the same and specified time intervals for clinical re-evaluation and sinus endoscopy. In these consultations, which take place one month, three months and six months after surgery, all patients are evaluated with SNOT22 and Lund Kennedy questionnaires, and the patients' information is recorded. In other words, the follow-up period of patients will be 6 months. Also, patients will be checked for drug side effects after starting the treatment. The evaluated side effects of Clarithromycin include abdominal pain, diarrhea, nausea, vomiting, dyspepsia, anorexia, headache, Dysgeusia, allergic reactions and hearing loss.
Category
Treatment - Drugs

3

Description
Placebo + placebo group: patients receiving standard chronic rhinosinusitis (CRS) treatment : After endoscopic functional sinus surgery, 64 patients assigned to this group were treated for at least three weeks with placebo tablets and placebo capsules along with the standard chronic rhinosinusitis regimen (nasal irrigation with physiological serum, fluticasone steroid spray two puffs in the morning and night). The failure or success of treatment will be evaluated through clear reduction of signs and symptoms, improvement of quality of life and prevention of progression or recurrence of the disease based on endoscopic findings and by continuous follow-up. All patients refer to Amir al-Momenin Hospital on an outpatient basis at the same and specified time intervals for clinical re-evaluation and sinus endoscopy. In these consultations, which take place one month, three months and six months after surgery, all patients are evaluated with SNOT22 and Lund Kennedy questionnaires, and the patients' information is recorded. In other words, the

follow-up period of patients will be 6 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Mo'menin Educational Remedial & Research Center

Full name of responsible person

Dr. Ali Faghih Habibi

Street address

17th Shahrivar St. Dr. Heshmat Sq.

City

Rasht

Province

Guilan

Postal code

4139637459

Phone

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Email

amiralmomenin@gums.ac.ir

Web page address

https://amir.gums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipour

Street address

Deputy of Research and Technology, in front of 17 Shahrivar Hospital, Namjoo St.

City

Rasht

Province

Guilan

Postal code

4193713191

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Ali Faghih Habibi

Position

Head of Amir Al Mo'menin Hospital, Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

17th Shahrivar St. Dr. Heshmat Sq.

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Ali Faghih Habibi

Position

Head of Amir Al Mo'menin Hospital, 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
Rasht University of Medical Sciences

Full name of responsible person
Dr. Enayatollah Gholamalian

Position
ENT Resident

Latest degree
Medical doctor

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

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

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

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

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