Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of doxycycline in chronic rhinosinusitis with nasal polyps

Protocol summary

Study aim
To determine the effect of doxycycline in chronic rhinosinusitis with nasal polyps

Design
A clinical trial study with control group, parallel groups, double-blinded, randomized with block randomization, phase 3 on 90 patients.

Settings and conduct
This study is performed on 90 patients in Hazrat Rasool Hospital. Patients are randomly divided into intervention group and control group. Blindnig will be performed on patients, researcher, and outcome assessor. Patients are assessed for quality of life, symptoms severity, peak nasal inspiratory flow, total serum IgE, peripheral eosinophil count, nasal mucosal eosinophil count and nasal polyp size.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic rhinosinusitis with nasal polyps who have moderate to severe disease and are 18 to 60 years old; Exclusion criteria: Pregnancy, Breast feeding, sinus surgery within the last 3 months, antibiotic consumption within the last month, History of allergic reaction to doxycycline, renal failure or liver failure, Warfarin consumption.

Intervention groups
Intervention group: Nasal fluticasone spray, Montelukast and nasal irrigation as baseline treatment and oral enteric coated doxycycline (Behshad Darou, Iran) 200 Mg on day 1 then 100 Mg daily for 6 weeks. Control group: Nasal fluticasone spray, Montelukast and nasal irrigation as baseline treatment and placebo two capsules on day 1 then one capsule daily for 6 weeks.

Main outcome variables
Quality of life based on Sino-Nasal Outcome Test 22 (SNOT22), symptoms severity, peak nasal inspiratory flow and nasal polyp size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210403050817N1**
Registration date: **2021-05-29, 1400/03/08**
Registration timing: **prospective**

Last update: **2021-05-29, 1400/03/08**
Update count: **0**

Registration date
2021-05-29, 1400/03/08

Registrant information

Name
Fatemeh Atashrazm

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6655 4933

Email address
atashrazm.f@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-31, 1400/03/10

Expected recruitment end date
2021-12-01, 1400/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of doxycycline in chronic rhinosinusitis with nasal polyps

Public title
Effect of doxycycline in nasal polyps

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic rhinosinusitis with nasal polyps Age between 18 to 60 years Moderate to severe disease
Exclusion criteria:
Pregnancy Breast feeding Allergy to doxycycline History of sinus surgery within the last 3 months Antibiotic consumption within the last month Liver failure Renal failure Warfarin consumption
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization is done using the sealedenvelope.com site with a block size of 4 and considering a unique code for each participant. For concealment, the drug for each individual is placed in a sealed and opaque envelope and a unique code is pasted on it.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is performed for the following levels in this study. Patient: Placebo is used, which is similar to the main drug in terms of color, shape, appearance and smell. Researcher and outcome assessor: A placebo is used that is similar to the main drug in color, shape, appearance and smell. The received intervention is indicated by a code and the researcher is not aware of the codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Medicine, Iran University of Medical Sciences
Street address
Faculty of medicine, Iran University of Medical Sciences, Shahid Hemmat Highway, Next to Milad tower
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-01-27, 1399/11/08
Ethics committee reference number
IR.IUMS.FMD.REC.1399.850

Health conditions studied

1

Description of health condition studied
Chronic Rhinosinusitis with Nasal Polyps
ICD-10 code
J33
ICD-10 code description
Nasal polyp

Primary outcomes

1

Description
Quality of life based on Sino-Nasal Outcome Test 22 (SNOT-22) questionnaire
Timepoint
Beginning of the intervention, At the end of the intervention (6 weeks later) and 4 weeks after treatment completion
Method of measurement
Sino-Nasal Outcome Test 22 (SNOT-22) questionnaire

Secondary outcomes

1

Description
Nasal congestion score based on visual analogue scale
Timepoint
Beginning of the intervention, At the end of the intervention (6 weeks later) and 4 weeks after treatment completion
Method of measurement
Visual Analogue Scale

2

Description
Score of decreased sense of smell based on visual analogue scale
Timepoint
Beginning of the intervention, At the end of the

intervention (6 weeks later) and 4 weeks after treatment completion

Method of measurement

Visual Analogue Scale

3

Description

Anterior nasal discharge score based on visual analogue scale

Timepoint

Beginning of the intervention, At the end of the intervention (6 weeks later) and 4 weeks after treatment completion

Method of measurement

Visual Analogue Scale

4

Description

Posterior nasal discharge score based on visual analogue scale

Timepoint

Beginning of the intervention, At the end of the intervention (6 weeks later) and 4 weeks after treatment completion

Method of measurement

Visual Analogue Scale

5

Description

Peak nasal inspiratory flow (PNIF)

Timepoint

Beginning of the intervention, At the end of the intervention (6 weeks later)

Method of measurement

Peak nasal inspiratory flow meter

6

Description

Nasal polyp size

Timepoint

Beginning of the intervention, At the end of the intervention (6 weeks later)

Method of measurement

Lund-MacKay score on low-dose CT scan

Intervention groups

1

Description

Intervention group: Nasal Fluticasone Spray 100 micrograms twice daily, oral Montelukast 10 mg daily, Nasal irrigation, oral Doxycycline (manufactured by Behshad Darou, Iran) 200 mg on day 1 then 100 mg daily for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Nasal Fluticasone Spray 100 micrograms twice daily, oral Montelukast 10 mg daily, Nasal irrigation, oral Placebo (manufactured by Behshad Darou, Iran) two capsules on day 1 and then one capsule daily for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool hospital

Full name of responsible person

Fatemeh Atashrazm

Street address

Hazrat Rasool hospital, Niayesh St, Sattarkhan Ave,

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6655 4933

Fax

+98 21 6655 4933

Email

dr.atashrazm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevalian

Street address

Deputy of research and technology, Iran University of Medical Sciences, Shahid Hemmat Highway, Next to Milad tower

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Fax

+98 21 8862 2703

Email

motevalian.a@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Atashrazm
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Allergy and Clinical Immunology
Street address
Hazrat Rasool hospital, Niayesh St, Sattarkhan Ave
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
dr.atashrazm@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Nabavi
Position
Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Allergy and Clinical Immunology
Street address
Hazrat Rasool hospital, Niayesh St, Sattarkhan Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
Mnabavi44@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Atashrazm
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Allergy and Clinical Immunology
Street address
Hazrat Rasool hospital, Niayesh St, Sattarkhan Ave
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6655 4933
Fax
+98 21 6655 4933
Email
dr.atashrazm@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified Individual Participant Data can be shared.
When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Individual participant data only available for people working in academic institutions

Under which criteria data/document could be used

-

From where data/document is obtainable

Dr. Fatemeh Atashrazm email address dr.atashrazm@gmail.com

What processes are involved for a request to access data/document

Data will be sent 1 month after receiving the email

Comments