

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of the effect of oral curcumin on reducing the recurrence of nasal polyposis in patients undergoing endoscopic sinus surgery

Protocol summary

Study aim

The aim of the study will be determine and compare the effect of curcumin and placebo on recurrence of nasal polyposis in patients undergoing endoscopic sinus surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 36 patients. The envelope method will be used for randomization.

Settings and conduct

study will be performed at Besat Hospital in Hamedan on patients with chronic rhinosinusitis and nasal polyps. Patients will undergo functional endoscopic sinus surgery and polypectomy. After surgery, all patients will take Fluticasone spray, Montelukast tablets, and Cefixime 400 mg capsules as prescribed by the doctor. One group will take capsule containing 500 mg of curcumin and the other group will take a capsule containing starch daily/ months orally. Both groups will be examined at the end of the 1, 4 and 6 month post operation in terms of polyp recurrence and pain score.

Participants/Inclusion and exclusion criteria

The age of 18 to 60 years and suffering from chronic rhinosinusitis comorbidity with nasal polyps are the conditions for entering the study and the history of allergy to curcumin , the presence of immune system disorders and suffering from systemic diseases are the criteria for not entering the study.

Intervention groups

The first intervention group: after endoscopic surgery of chronic sinusitis and splenectomy, along with routine care, they will take a capsule containing 500 mg of curcumin orally for 2 months. The second intervention group: after endoscopic surgery of chronic sinusitis and splenectomy, along with routine care, they will take a capsule containing 500 mg of starch orally for 2 months.

Main outcome variables

Recurrence of nasal polyps, recurrence of sinusitis and changes in pain score caused by chronic sinusitis will be

the main outcomes of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N24**

Registration date: **2022-10-24, 1401/08/02**

Registration timing: **prospective**

Last update: **2022-10-24, 1401/08/02**

Update count: **0**

Registration date

2022-10-24, 1401/08/02

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral curcumin on reducing the recurrence of nasal polyposis in patients undergoing endoscopic sinus surgery

Public title

Effect of oral curcumin on reducing the recurrence of nasal polyposis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with chronic sinusitis resistant to drug treatment
Having nasal polyps

Exclusion criteria:

Having an allergy to turmeric
Immunodeficiency problem
Suffering from systemic diseases such as diabetes, renal failure, malignancies, cystic fibrosis and granulomatous diseases.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

36 cards are prepared and on 18 cards the letter C means curcumin and on the other 18 the letter P means placebo is written and each one is put inside an envelope with aluminum foil and the lid is glued and placed inside a box. At the time of patients' arrival, one of the envelopes will be randomly selected and opened. According to the selected letter (C or P) inside the envelope, the patient will be assigned to the curcumin or placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Capsules containing curcumin and placebo will be prepared with the same packaging. The contents of the packages are marked with a code, and the patient and the person evaluating the outcome of the treatment will be unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Science

Street address

Hamadan University of Medical Science, Shahid fahmideh Ave, Hamadan

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6517838697

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.UMSHA.REC.1401.505

Health conditions studied**1****Description of health condition studied**

nasal polyposis

ICD-10 code

J33

ICD-10 code description

Nasal polyp

Primary outcomes**1****Description**

Relapse of polype

Timepoint

Before treatment, 1 month, 4 months and 6 months after treatment

Method of measurement

Nasal endoscopy

Secondary outcomes**1****Description**

Treatment Complication

Timepoint

1, 2 and 6 months after treatment

Method of measurement

Visual Analogue Score (VAS)

Intervention groups

1

Description

Intervention group: Patients with chronic sinusitis resistant to treatment after endoscopic sinus surgery, in addition to routine post-treatment care and follow-up, take a 500 mg curcumin capsule daily for 2 months prepared at Hamedan Pharmacy School.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: Patients with chronic sinusitis resistant to treatment after endoscopic sinus surgery, in addition to routine post-treatment care and follow-up, take a capsule containing starch (placebo) daily for 2 months prepared at Hamedan Pharmacy School.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

dr Javane Jahanshahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Reza Shokohi

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Medical Schol

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

Epidemiology

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inquiries

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Latest degree

Subspecialist

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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

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master