Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
Hamedan University of Medical Of Science

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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 cocumine 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 Univercity of Medical Science

Street address
Hamadan Univercity of Medical Science, Shahid fahmideh Ave, Hamadan

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Province
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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
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Sponsors / Funding sources

1

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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/ Comunity Medicine MS
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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