

# 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

+98 81 3838 0097

##### Email address

a.moradi@umsha.ac.ir

##### 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 University of Medical Science

**Street address**

Hamadan University of Medical Science, Shahid fahmideh Ave, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

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

##### Street address

shahid Beheshti Blvd

##### City

Hamedan

##### Province

Hamadan

##### Postal code

6514845411

##### Phone

+98 81 3264 0030

##### Fax

+98 81 3265 1515

##### Email

jahanshahi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

dr Reza Shokohi

##### Street address

Shahid Fahmide Ave

##### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838677

#### Phone

+98 81 3838 0717

#### Fax

+98 81 3838 0130

#### Email

vc\_research@umsha.ac.ir

#### 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

##### Street address

Hamadan, Shahid Fahmideh Avenue, Medical School,  
Department of Social Medicine

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##### Province

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##### Phone

+98 81 3838 0557

##### Fax

##### Email

a.moradi@umsha.ac.ir

##### Web page address

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Javaneh Jahanshahi

**Position**

Department of ENT

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Web page address**

### **Other areas of specialty/work**

Epidemiology

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### **Province**

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### **Fax**

### **Email**

a.moradi@umsha.ac.ir

### **Web page address**

## **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