Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Curcumin on the improvement of patients undergoing rhinoplasty

Protocol summary

Study aim

General purpose: Determining the effect of Curcumin on improving the symptoms of patients undergoing rhinoplasty surgery

Design

Clinical trial with control group with parallel and double-blind, randomized phase 3 phase on 110 patients
Random number table was used for randomization

Settings and conduct

After obtaining informed written consent from patients with inclusion criteria in Alzahra hospital 110 patients are selected and included in the study.Patients will then be divided into two equal groups with random allocation software 1.0 . The first group will receive a placebo as a control and the second group will receive curcumin.The drug is started in the form of 500 mg capsules daily for two weeks.For patients in the placebo group, the drug is prepared in the same style and form of the main drug, and the same form of drug is started.For blinding drugs and placebo are placed in special packages and numbers A and B are placed. The person prescribing the drug, the patient and the person analyzing the drug have no information about the type of drug.Data collection tools in this study are Sino-nasal Outcome Test (SNOT-22) scale and NOSE (nasal obstruction septoplasty effectiveness) scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients undergoing rhinoplasty due to dissatisfaction with the shape of the nose 2. No history of allergy to Curcumin 3- Satisfaction to participate in this study 4. No sinusitis 5. No nasal polyps 6. No systemic diseases 7. No MS 8. No cleft lip or palate or both 9- No space-absorbing mass in the nose Criteria for not entering: 1. Do not use medicine 2. Do not use other anti-inflammatory drugs

Intervention groups

Intervention group of patients who are given Curcumin
Control group of patients who are given placebo

Main outcome variables

SNOT-22 score, NOSE score, Duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048463N1**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-19, 1399/08/29**
Update count: **0**

Registration date

2020-11-19, 1399/08/29

Registrant information

Name

Ahmad Rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3223 4622

Email address

dr.ahmadrezaeian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-17, 1399/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Curcumin on the improvement of patients undergoing rhinoplasty

Public title
The effect of Curcumin on the improvement of patients undergoing nose surgury

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing rhinoplasty due to dissatisfaction with the shape of the nose No history of allergy to Curcumin Satisfaction to participate in this study No sinusitis No nasal polyps No systemic diseases No MS No cleft palate or lips or both Lack of space-absorbing mass in the nose
Exclusion criteria:
Do not use medicine Do not use other anti-inflammatory drugs

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
110 patients who meet the inclusion criteria are admitted to the study as unlikely and easy, and the treatment is assigned to two groups randomly with the help of web-based randomization. To do this, the website www.grphpad.com is used to generate a random sequence for two-group trials. The unit is an individual randomization. First, the names of all 110 patients are prepared as a list and are numbered from one to one hundred and ten, respectively. In the second step, in the new randomization section of the website, enter the number of people in each sample, which is 55, and then press the button. Web site sequencing equates one to one hundred and ten options A or B equally. Individuals assigned to group A are treated with curcumin and those assigned to group B are treated with medication. They will be placed on the facade

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, researchers, and outcome evaluators and data analysts do not know which group every person belong toIn such a way that an independent person is selected as a random divider of patients and a distributor of drugs among selected patients, the doctor refers each patient to that person and he / she, based on the random list he / she has prepared, gives each patient the medicine that should be in his / her group. To receive

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hzarjerib street
City
Esfahan
Province
Isfehan
Postal code
9987654213

Approval date
2020-02-01, 1398/11/12

Ethics committee reference number
IR.MUI.MED.REC.1398.565

Health conditions studied

1

Description of health condition studied
Evaluation of the effect of curcumin on the recovery of patients after rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nasal obstruction septoplasty effectiveness(NOSE) score

Timepoint
Before, one week, two weeks and one month after surgery

Method of measurement
NOSE scale

2

Description
Sino nasal outcome test 22 (SNOT22) score

Timepoint

Before, one week, two weeks and one month after surgery

Method of measurement

SNOT22 scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Curcumin reciverFor this group of patients Curcomax capsules should be given, it is considered that this capsule was made by Health Company in England, and each 500 mg capsule contains 400 mg of turmeric extract or root. The patient has been taking one of these oral capsules daily since the day after surgery and has been taking this medicine for a month.

Category

Treatment - Drugs

2

Description

Control group: Placebo receiverFor this group of patients, placebo medicine with the same shape, weight, color and packaging has been prepared by the same company, and each patient uses a 500 mg placebo capsule daily from the first day after surgery and takes this medicine for a long time. Consumes a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Doctor Ahmad Rezaeian

Street address

Sofe street

City

Esfahan

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Isfehan

Postal code

9987654449

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+98 31 3792 3456

Email

Alzahra@email.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Doctor Fereshte Haghjoo

Street address

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esfahanunivercicty@email.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Doctor Ahmad rezaeian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ahmad Rezaeian

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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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 data can be published

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
All

Under which criteria data/document could be used
Nothing

From where data/document is obtainable
Isfahan University of Medical Sciences

What processes are involved for a request to access data/document
By referring to the university library, the Taza form is registered and the data is given

Comments