

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparing the effectiveness of two methods of radiofrequency and outfracture of the hypertrophic inferior turbinate in improving the breathing of rhinoplasty patients in Al-Zahra and Kashani hospitals.

Protocol summary

Study aim

Comparing the effectiveness of two methods of radiofrequency and outfracture of the hypertrophic inferior turbinate in improving breathing in rhinoplasty patients

Design

This study will be conducted as a phase 3 clinical trial with two intervention groups in parallel. Patients are randomly assigned to one of the two study groups with the help of a random number table, and blinding has not been achieved. The approximate size of each study group will be 30 people.

Settings and conduct

This study will be conducted as a clinical trial in 1402 in the city of Isfahan in Kashani and Al-Zahra Hospital of Isfahan. It is not blinded. Two treatment methods, radiofrequency and outfracture, will be investigated in the treatment of inferior turbinate enlargement.

Participants/Inclusion and exclusion criteria

People participating in this study include people with hypertrophic inferior turbinate who are candidates for rhinoplasty who give informed consent to participate in the study. People with underlying diseases such as blood pressure and coagulation disorders and people with a BMI higher than 35 will not be included in the study.

Intervention groups

In this study, there will be two types of intervention in two study groups. The first group, who undergo rhinoplasty, will have their lower turbinate reduced by the outfracture method; And the second group will shrink their lower turbine using radio frequency method.

Main outcome variables

Quality of life and improvement of patients' symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230303057601N1**
Registration date: **2023-03-10, 1401/12/19**
Registration timing: **prospective**

Last update: **2023-03-10, 1401/12/19**

Update count: **0**

Registration date

2023-03-10, 1401/12/19

Registrant information

Name

Amirabas Kargoshaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3628 3485

Email address

kargoshaie@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of two methods of

radiofrequency and outfracture of the hypertrophic inferior turbinate in improving the breathing of rhinoplasty patients in Al-Zahra and Kashani hospitals.

Public title

Radiofrequency and hypertrophic inferior turbinate outfracture in rhinoplasty patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Candidate for rhinoplasty Hypertrophic inferior turbinate

Exclusion criteria:

Underlying diseases such as hypertension, diabetes, coagulative disorders BMI over 35

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in the form of a table of random numbers. The first hypothesis is to move from the table to the top, and the second hypothesis is to assign even numbers to the first group and odd numbers to the second group. In this method, the researcher selects a number on the table for each patient in the order of entering the study and moves up, and in the order of entry, each patient is assigned a number, and if the patient's number is even in the group, one and if it is odd It is placed in group two.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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 science

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-12-22, 1401/10/01

Ethics committee reference number

IR.MUI.MED.REC.1401.411

Health conditions studied

1

Description of health condition studied

Inferior turbinate hypertrophy and rhinoplasty

ICD-10 code

J34.3

ICD-10 code description

Hypertrophy of nasal turbinates

Primary outcomes

1

Description

Quality of life and symptoms

Timepoint

Before and 1 and 3 months after treatment

Method of measurement

Snott 22 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: radiofrequency in treatment of hypertrophic inferior turbinate

Category

Treatment - Surgery

2

Description

Intervention group: outfracture treatment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Faeze Keshtkar
Street address
Kashani
City
Isfahan
Province
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Postal code
8174673461
Phone
+98 31 3668 0048
Email
vcr-office@med.mui.ac.ir

2

Recruitment center

Name of recruitment center
Alzahra hospital
Full name of responsible person
Faeze Keshtkar
Street address
Hezar Jarib
City
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Postal code
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+98 31 3668 0048
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vcr-office@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice President of Research and Research of Isfahan
University of Medical Sciences
Street address
Hazar Jarib
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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

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
Faeze Keshtkar
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resident
Latest degree
Medical doctor
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Person responsible for updating data

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Full name of responsible person

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Position

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Medical doctor

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information is available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available