Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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
Isfehan
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
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
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
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
vcr-office@med.mui.ac.ir
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
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
dr_f1990@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Faeze Keshtkar
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone

0313680048

Email

dr_f1990@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Faeze Keshtkar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

dr_f1990@yahoo.com

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