

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

To compare the impact of microdebrider assisted inferior turbinoplasty vs inferior turbinate cauterization on the quality of life of children

Protocol summary

Study aim

To compare the impact of microdebrider assisted inferior turbinoplasty vs inferior turbinate cauterization on the quality of life of children.

Design

A randomized double-blind clinical trial study with a control group, with parallel design on 54 patients. Block randomization method will be used for randomization.

Settings and conduct

Shahid Dastgheib hospital affiliated to Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients under 18 years of age with inferior turbinate hypertrophy who complained of nasal congestion and rhinorrhea in rhinoscopy and did not respond well to oral or topical corticosteroids, antihistamines, and other conservative methods, who were candidate for turbinate reduction surgery included in this study.

Intervention groups

first: microdebrider assisted inferior turbinoplasty
second: inferior turbinate cauterization

Main outcome variables

quality of life of children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131020015083N3**

Registration date: **2021-11-30, 1400/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-30, 1400/09/09**

Update count: **0**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Amir Hossein Babaei

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-23, 1400/09/02

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the impact of microdebrider assisted inferior turbinoplasty vs inferior turbinate cauterization on the quality of life of children

Public title

To compare the impact of microdebrider assisted inferior turbinoplasty vs inferior turbinate cauterization

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

inferior turbinate hypertrophy nasal congestion Existence of rhinorrhea Failure to respond to medications including oral or topical corticosteroids, antihistamines

Exclusion criteria:
Age more than 18 years Adenoid hypertrophy Nasal polyps Severe deviation of the nasal septum

Age
To 18 years old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: 27

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned to microseprider assisted inferior turbinoplasty (number 0 in select case) or inferior turbinate cauterization (number 1 in select case) groups (1: 1 ratio) using random numbers which were generated through computerized block randomization using SPSS software version 23. To reduce selection bias and confounding factors, randomization was performed by a single appointed researcher who did not participate in data collection.

Blinding (investigator's opinion)
Double blinded

Blinding description
patients, outcome assessor, and statisticians who analyzed the data were unaware of the intervention and allocation of treatments until the statistical analysis was complete.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand Street

City
shiraz

Province
Fars

Postal code
71348-14336

Approval date

2021-10-30, 1400/08/08
Ethics committee reference number
IR.SUMS.MED.REC.1400.401

Health conditions studied

1

Description of health condition studied
children with hypertrophy of nasal turbinates

ICD-10 code
J34.3

ICD-10 code description
Hypertrophy of nasal turbinates

Primary outcomes

1

Description
Patients' quality of life

Timepoint
1, 3 and 6 months after surgery

Method of measurement
SNOT-22 Questionnaire

2

Description
Presence of crust in nasal cavity

Timepoint
Up to 1 week after surgery

Method of measurement
Anterior rhinoscopy

Secondary outcomes

1

Description
Postoperative nasal bleeding

Timepoint
Up to 1 week after surgery

Method of measurement
Anterior rhinoscopy

2

Description
Facial pain

Timepoint
Up to 1 week after surgery

Method of measurement
Question from the patient

3

Description
Bad smell in nose

Timepoint
Up to 1 week after surgery

Method of measurement

Question from the patient

Intervention groups

1

Description

Intervention group: microdebrider assisted inferior turbinoplasty

Category

Treatment - Surgery

2

Description

Intervention group: inferior turbinate cauterization

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Dr. Tayebbeh Kazemi

Street address

Hafez street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

22804

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Tayebbeh Kazemi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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resident

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Medical doctor

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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

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

Yes - There is 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

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions.

Under which criteria data/document could be used

there is no specified criteria

From where data/document is obtainable

corresponding author (salmanp445@gmail.com; 09179871643)

What processes are involved for a request to access data/document

the request should be sent by email (containing personal and professional information), describing their study protocol, after approving their identity and proposal, the data will be sent by email.

Comments