

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effect of triamcinolone acetate injection in the lower branches of the nose in improving the symptoms and quality of life of patients with allergic rhinitis undergoing rhinoplasty

Protocol summary

Study aim

Determination of mean score of symptoms and quality of life in the intervention group with triamcinolone before and after intervention Determination of mean score of symptoms and quality of life in control group before and after intervention Comparison of mean score of symptoms and quality of life after intervention in two groups

Design

In this study, 100 patients who have undergone rhinoplasty due to allergic rhinitis who are referred to Khatam-ol-Anbia Hospital will be included in the study after explaining the study conditions and obtaining informed consent. After completing the rhinoplasty, the patients completed the questionnaire before the rhinoplasty, and randomly (by selecting a card from inside the bag containing 50 A cards and 50 B cards) into two groups receiving triamcinolone and the control group , Will be divided.

Settings and conduct

In this study, 100 patients who have undergone rhinoplasty due to allergic rhinitis who visit Khatam-ol-Anbia Hospital will be included in the study after explaining the study conditions and obtaining informed consent. After completing the rhinoplasty, the patients completed the questionnaire before the rhinoplasty, and randomly (by selecting a card from inside the bag containing 50 A cards and 50 B cards) into two groups receiving triamcinolone and the control group . In the recipient group, 20 mg of triamcinolone per day will be injected into each lower nasal concha, and no drug will be used in the control group. Finally, one month after injection, symptoms and quality of life of patients are calculated using the standard questionnaire of symptoms and quality of life in patients with allergic rhinitis and will be recorded in a form of information. Blind: Due to the fact that the intervention is performed during and after

anesthesia, the intervention or non intervention group does not know about the intervention.

Participants/Inclusion and exclusion criteria

Major entry into the study includes all patients who undergo rhinoplasty as a result of allergic rhinitis. Major exclusion criteria include a history of respiratory infections in the past 1 month, systemic illness, alcohol consumption, pregnancy or lactation, corticosteroid therapy, mental disorder.

Intervention groups

in intervention group,20 mg of triamcinolone per day will be injected into each lower nasal concha, and no drug will be used in the control group.

Main outcome variables

Determination of the effect of triamcinolone acetate injection on the lower branches of the nose in improving symptoms and quality of life of patients with allergic rhinitis under rhinoplasty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171008036655N2**

Registration date: **2018-02-23, 1396/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**

Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 750 5055

Email address

m.mohammadi1370@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of triamcinolone acetate injection in the lower branches of the nose in improving the symptoms and quality of life of patients with allergic rhinitis undergoing rhinoplasty

Public title

Investigating the effect of triamcinolone acetate injection in the lower branches of the nose in improving the symptoms and quality of life of patients with allergic rhinitis undergoing rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Major entry into the study includes all patients undergoing rhinoplasty due to allergic rhinitis in year 96-97.

Exclusion criteria:

Major exclusion criteria include a history of respiratory infections in the past 1 month, systemic illness, alcohol consumption, pregnancy or lactation, corticosteroid therapy, mental disorder.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment method: For random assignment, 50 cards A and 50 cards B are inserted into the bag and after completing the pre-operation questionnaires, the patient is asked to remove one of these cards if the card A is selected The intervention group and if the card B is selected, it will be allocated to the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the intervention is performed during and after anesthesia, the intervention or non-intervention group is not aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan, Dr. Hassabi Square, Persian Gulf Blvd, Campus Complex, Zahedan University of Medical Sciences and Health Services

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

3000123155

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.ZAUMS.REC.1396.127

Health conditions studied

1

Description of health condition studied

allergic rhinitis

ICD-10 code

J30.8

ICD-10 code description

Other allergic rhinitis

Primary outcomes

1

Description

Score of symptoms and quality of life

Timepoint

Complete the questionnaires before and one month after the injection

Method of measurement

Standard questionnaire of symptoms and quality of life in patients with rhinoconjunctivitis

Secondary outcomes

1

Description

Score of symptoms and quality of life

Timepoint

Complete the questionnaires before and one month after the injection

Method of measurement

Standard questionnaire of symptoms and quality of life in patients with rhinoconjunctivitis

Intervention groups

1

Description

Intervention group: In the intervention group, 20 mg of triamcinolone will be given intraoperatively in each lower nasal concha.

Category

Treatment - Surgery

2

Description

Control group: No drugs will be used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia Hospital

Full name of responsible person

Dr. Gholamali Dashti

Street address

Khatam Al Anbia Hospital, Jam Jam Street, Zahedan

City

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Sistan-va-Balouchestan

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3000709050

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Fax

Email

drdashti50@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Hooshang Rafiqdoust

Street address

Office of Health Services, Persian Gulf Blvd, Dr. Hesabi Square, Zahedan

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mohamad.mohamadi1370@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Dashti

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Dashti

Position

ENT

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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