

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

3000709050

##### Phone

+98 54 3322 0501

##### 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

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

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#### Phone

+98 54 3329 5715

#### Email

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

##### Street address

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

##### City

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##### Province

Sistan-va-Balouchestan

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3000123155

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+98 54 3329 5715

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drdashti50@yahoo.com

## 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**

Ear, Nose, and Throat

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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

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamali Dashti

**Position**

ENT

**Latest degree**

Specialist