

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the effects of oral isotretinoin on the results of rhinoplasty (scar and cartilage shape) in patients with thick nasal skin.

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of oral isotretinoin on the surgical scars and changes in nasal cartilage in patients with thick skin who have undergone rhinoplasty

##### Design

Clinical trial with control group, parallel groups, phase 3 on 40 patients, simple randomization method using closed door envelope

##### Settings and conduct

This clinical trial is done in the Plastic surgery department of Imam Khomeini and Amir Alam Hospitals in Tehran on 40 patients for rhinoplasty with thick skin . Eligible patients are divided into control and intervention groups after obtaining consent, and in intervention group, in addition to routine treatment from 1 week before to two months after surgery, 20 mg isotretinoin tablets are taken orally 3 times a week, which in the control group performs only routine treatments. Finally, the results are entered into SPSS software and analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are candidates for primary rhinoplasty and have thick nasal skin. Exclusion criteria: absence of allergy to vitamin A, pregnancy decision from one month before taking one year later, breastfeeding, hyperlipidemia and liver and kidney diseases.

##### Intervention groups

The case group includes patients with thick nasal skin who underwent rhinoplasty and received isotretinoin tablets 20 mg 3 times a week from one week before to two months after the surgery. The control group includes patients with thick nasal skin who underwent rhinoplasty and did not receive medication.

##### Main outcome variables

Scars and deformation of cartilage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240204060896N1**  
Registration date: **2024-02-11, 1402/11/22**  
Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

##### Registration date

2024-02-11, 1402/11/22

##### Registrant information

##### Name

Maryam Nazari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 9904

##### Email address

maryam\_nazari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-04, 1402/11/15

##### Expected recruitment end date

2024-06-04, 1403/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of oral isotretinoin on the results of rhinoplasty (scar and cartilage shape) in patients with thick nasal skin.

**Public title**

Effect of isotretinoin on the results of rhinoplasty

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with thick nasal skin Patients undergo rhinoplasty for the first time

**Exclusion criteria:**

Allergy to vitamin A Pregnancy or intention to become pregnant within the next year and breastfeeding (isotretinoin is contraindicated) Simultaneously suffering from liver, kidney and heart diseases (isotretinoin is contraindicated) Hyperlipidemia (isotretinoin is contraindicated) History of rhinoplasty Skin diseases that change the thickness of the nose, such as rhinophyma

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done in a simple way using a table of random numbers using [www.randomization.com](http://www.randomization.com). The numbers will be placed in closed envelopes, and upon entering, participants will be assigned an envelope and will be placed in one of 2 groups.

**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 Tehran University of Medical Science

**Street address**

Keshavarz Blvd, Ghods St

**City**

Tehran

**Province**

Tehran

**Postal code**

1416633591

**Approval date**

2023-10-10, 1402/07/18

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1402.286

**Health conditions studied****1****Description of health condition studied**

rhinoplasty

**ICD-10 code**

M95.0

**ICD-10 code description**

Acquired deformity of nose

**Primary outcomes****1****Description**

Scars

**Timepoint**

1month, 3 months and 6 months after surgery

**Method of measurement**

The method of variable measurement is qualitative, in the following way, in the follow-up visit after surgery, post-operative photos are taken and compared with preoperative photos by a plastic and reconstructive surgeon.

**2****Description**

deformation of nasal cartilage

**Timepoint**

1month, 3 months and 6 months after surgery

**Method of measurement**

The method of variable measurement is qualitative, in the following way, in the follow-up visit after surgery, post-operative photos are taken and compared with preoperative photos by a plastic and reconstructive surgeon.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In this group, from one week before to two months after surgery patients are treated with 20 mg isotretinoin table 3 times a week and the condition of scar and deformation of the nasal cartilage is evaluated 1, 3 and 6 months after consumption. Isotretinoin manufactured in Iran under the brand name NORMSKIN is used in the study.

**Category**

Treatment - Other

## 2

### Description

Control group: In this group, routine drugs are prescribed after surgery and isotretinoin is not prescribed.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Omid etemad

**Street address**

End of Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

3314114197

**Phone**

+98 21 6119 0000

**Email**

maryam\_nazari1@yhoo.com

### 2

#### Recruitment center

**Name of recruitment center**

Amir A'lam Hospital

**Full name of responsible person**

Omid etemad

**Street address**

North Saadi ST.

**City**

Tehran

**Province**

Tehran

**Postal code**

6511111457

**Phone**

+98 21 6634 3352

**Email**

maryam\_nazari1@yhoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Omid etemad

**Street address**

End of Keshavarz Boulevard

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**Phone**

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**Email**

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Omid Etemad

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Plastic and reconstructive surgery

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End of Keshavarz Boulevard

**City**

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**Phone**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Omid Etemd

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Omid Etemad

**Position**

Associate professor

**Latest degree**

Subspecialist

**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**

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