

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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_nazari1@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. 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

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3314114197

Phone

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2

Recruitment center

Name of recruitment center

Amir A'lam Hospital

Full name of responsible person

Omid etemad

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North Saadi ST.

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6511111457

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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

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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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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

Plastic and reconstructive surgery

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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