

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation the efficacy of topical isotretinoin after rhinoplasty in people with thick and oily skin of the nose

Protocol summary

Study aim

Evaluation the effectiveness of topical isotretinoin on the satisfaction of patients with thick and oily skin who have undergone rhinoplasty

Design

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

Settings and conduct

This double blind clinical trial (participants in the study and analyzers are blinded) is done in the ENT department of Ghaem Hospital in Mashhad on 40 patients for rhinoplasty with thick and oily skin . Eligible patients are divided into control and intervention groups after obtaining consent, and in intervention group, in addition to routine treatment one month after surgery, they take 0.05% isotretinoin gel topically every night, which in the control group performs only routine treatments. Finally, the results are entered into SPSS software and analyzed.

Participants/Inclusion and exclusion criteria

Candidates for rhinoplasty who do not have a history of skin allergies and do not decide to become pregnant from one month before use to one month after use and not being in Breastfeeding period.

Intervention groups

Patients with thick and oily skin diagnosed by a dermatologist and if they have inclusion criteria who underwent rhinoplasty surgery, Examined and photographed and after obtaining a whole history and completing the Demographics information form they are selected. In the control group, routine treatment recommendations is performed and in the intervention group, in addition to routine recommendations, one month after surgery, 0.05% isotretinoin gel (every night) is prescribed for 6 months.

Main outcome variables

Nasal edema and ecchymosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038763N3**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

mehdi bakhshae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3492

Email address

mehbakhsh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of topical isotretinoin after rhinoplasty in people with thick and oily skin of the nose	
Public title	Evaluation the effectiveness of isotretinoin in people with rhinoplasty with thick and oily skin
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Candidates for rhinoplasty who have thick and oily skin of the nose Conscious consent to participate in the study
Exclusion criteria:	Use of other medications in addition to prescribed medications Decide to get pregnant from one month before starting to one month after finishing Breastfeeding Dry and sensitive skin Incidence of skin allergies Use of drugs which have been shown to interact with isotretinoin
Age	From 18 years old to 50 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups
Blinding (investigator's opinion)	Double blinded
Blinding description	The subjects and those evaluating the outcome will be unaware of the intervention and control groups
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Mashhad University of Medical Science
Street address	Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City	Mashhad
Province	Razavi Khorasan
Postal code	9117699199
Approval date	2019-10-22, 1398/07/30
Ethics committee reference number	IR.MUMS.MEDICAL.REC.1400.036
Health conditions studied	
<u>1</u>	
Description of health condition studied	rhinoplasty
ICD-10 code	M95.0
ICD-10 code description	Acquired deformity of nose
Primary outcomes	
<u>1</u>	
Description	Edema and nasal ecchymosis
Timepoint	1month, 3 months and 6 months after surgery
Method of measurement	By an ENT specialist
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: In this group, in addition to routine treatment, 1 month after surgery patients are treated with 0.05% isotretinoin gel (every night) and the condition of nasal edema is evaluated 1, 3 and 6 months after consumption.
Category	Treatment - Other
<u>2</u>	
Description	Control group: In this group, routine recommendations include using oil-free sunscreen and skin trauma care and seeing a doctor in case of any side effects.
Category	Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mehdi Bakhshaei

Street address

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bakhshaeem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Morteza Noorollahian Mohajer

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

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