Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

: Evaluation of the effectiveness of plantago ovata on ecchymosis and edema after open rhinoplasty

Protocol summary

Study aim
Evaluation of the effectiveness of plantago ovata on ecchymosis and edema after open rhinoplasty

Design
A split body, double-blind, randomized, phase three clinical trial will be performed on 33 patients after rhinoplasty surgery. Excel software rand function was used for randomization.

Settings and conduct
A split body clinical trial study will be performed on 33 patients after blind bilateral rhinoplasty surgery at Modares Hospital affiliated to Shahid Beheshti University of Medical Sciences. Patients and physicians will be blind to the type of medication they receive.

Participants/Inclusion and exclusion criteria
Inclusion criteria will include: candidates for rhinoplasty surgery and informed consentExclusion criteria will include: pregnancy, heart and lung disease, people with a history of previous rhinoplasty, people with respiratory disease and asthma, and the use of other topical or oral medications for edema and ecchymosis.

Intervention groups
The intervention group includes one side of the nose in patients who have undergone open rhinoplasty surgery and after surgery will receive plantago ovata as a gel containing plantago ovata seeds prepared with the cooperation and approval of the International School of Pharmacy, Shahid Beheshti University. The opposite side of the nose in the same patients who have undergone open rhinoplasty surgery and after surgery will receive the same placebo gel, which is similar to the gel containing pomegranate seeds but has no properties.

Main outcome variables
Severity of edema, severity of eczema

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200523047549N2**
Registration date: **2022-05-11, 1401/02/21**
Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**
Update count: **0**

Registration date
2022-05-11, 1401/02/21

Registrant information

Name
Feizollah Niazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 8956

Email address
feizollahniazi2015@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
: Evaluation of the effectiveness of plantago ovata on ecchymosis and edema after open rhinoplasty

Public title

: Evaluation of the effectiveness of plantago ovata on ecchymosis and edema afterrhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All candidates for rhinoplasty Informed consent to participate in the study

Exclusion criteria:

Pregnancy of patients Heart and lung diseases People with a history of previous rhinoplasty Use of other local or oral medications for edema and ecchymosis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Random chain construction of two groups of 33A (intervention group) and B (control group) using Excel software will be used. In a column of 33 letters A and 33letters B and in the adjacent column with the Rand command, make 66 random numbers. Arrange both columns in random order from large to small. The sequence of letters A and B will be the random sequence used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of receiving ointment containing medication and placebo. Because the ointment containing the gel and the placebo are both given to patients in the same package, the doctor is also unaware of which side the patients used the medicine for. Therefore, the study will be two-way blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine Shahid Beheshti University of Medical Sciences

Street address

Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.SBMU.MSP.REC.1400.798

Health conditions studied

1

Description of health condition studied

Echymosis and Edema

ICD-10 code

Y81.3

ICD-10 code description

Surgical instruments, materials and general- and plastic-surgery devices (including sutures) associated with adverse incidents

Primary outcomes

1

Description

Severity of edema

Timepoint

8 hours after surgery, 16 hours after surgery, 24 hours and 48 hours after rhinoplasty

Method of measurement

Physical and clinical evaluation based on Pitting Edema criteria

2

Description

Severity of ecchymosis

Timepoint

8 hours after surgery, 16 hours after surgery, 24 hours and 48 hours after rhinoplasty

Method of measurement

Physical and clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group includes one

side of the nose in patients who have undergone open rhinoplasty surgery and after surgery will receive asparagus seeds as a gel containing asparagus seeds prepared with the cooperation and approval of the International School of Pharmacy, Shahid Beheshti University. will be.

Category

Treatment - Other

2

Description

Control group: The control group on the opposite side of the nose will be in the same patients who have undergone open rhinoplasty surgery and after surgery will receive the same placebo gel, which is similar to the gel containing pomegranate seeds but has no properties.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Farzad Ghotbi

Street address

Novel, Educational · Address: Tehran, Yadegar Imam Highway, Saadat Abad Intersection, Shahid Modares Hospital

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3438319987

Phone

+98 21 2207 4087

Email

ghotbi.farzad99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Chamran Highway Yemen St. - Shahid Arabi St. - Building No. 2 - Fifth Floor, Tehran

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1985717443

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Feizollah Niazi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study results, data and statistical codes will be published through reports and articles.
When the data will become available and for how long
Access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Access to the data with the permission of the person in charge of the study is allowed only for scientific research.
From where data/document is obtainable
Correspondence with the researcher via email
What processes are involved for a request to access data/document
Request from the study researcher, one month after the request.
Comments