

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 consent. Exclusion 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 after rhinoplasty

### **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 33 letters 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**

Ecchymosis 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

**City**

Tehran

**Province**

Tehran

**Postal code**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2243 9780

**Email**

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

**Street address**

Yadegar Imam Highway, Saadat Abad Intersection, Tehran Province

**City**

Tehran

**Province**

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**Postal code**

1998734383

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**Email**

feizollahniazi2015@sbmu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Feazollah Niazi

**Position**

Associate professor

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Subspecialist

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farzad Ghotbi

**Position**

Assitant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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ghotbi.farzad99@gmail.com

**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**