Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluating the efficacy of Pistacia Atlantica on ecchymosis and edema after rhinoplasty surgery, a randomized clinical trial

Protocol summary

Study aim
to determine the effect of Pistacia Atlantica oil on bruising and swelling after rhinoplasty on the patients who refer to Zahedan cosmetic surgery centers

Design
clinical trial with a control and placebo group, randomized, single-blind, sample size: 60 patients

Settings and conduct
People who go to Dr. Dashti's Otolaryngology clinic for rhinoplasty surgery and undergo rhinoplasty surgery in 1402 will be included in the study according to the entry and exit criteria and after obtaining informed consent. . 60 patients are included in the study. Patients are randomly divided into intervention and control groups.It is recommended to the patients after the surgery twice a day to oil the upper part of the cheek and the bruised areas completely with half a milliliter (10 drops) of oil. The packaging of Pistacia Atlantica oil and paraffin will be exactly the same. Follow-up of patients will be done on the third, fifth and seventh days after the surgery in terms of severity of bruising and swelling

Participants/Inclusion and exclusion criteria
criteria for entering the study: having informed and free consent regarding the objectives of the research, not having underlying diseases such as coagulation disorders, heart and lung diseases, not taking contraceptives and aspirin before the operation Exclusion criteria: occurrence of uncontrollable allergic symptoms such as moderate to severe itching, or skin reactions such as skin rashes due to the consumption of caraway oil

Intervention groups
drug: 10 ml of Pistacia Atlantica oil. Control group: placebo: liquid paraffin. Main outcome variables: severity Swelling, severity of bruising

Main outcome variables
Edema severity ; Ecchymosis severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054880N1**
Registration date: **2023-09-16, 1402/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-16, 1402/06/25**
Update count: **0**

Registration date
2023-09-16, 1402/06/25

Registrant information

Name
Zahra Sarani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 903 428 4838

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rahil19975@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2023-10-02, 1402/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the efficacy of Pistacia Atlantica on ecchymosis and edema after rhinoplasty surgery, a randomized clinical trial

Public title
Evaluating the efficacy of Pistacia Atlantica on ecchymosis and edema after rhinoplasty surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
having informed and free consent regarding the objectives of the research, not having underlying diseases such as coagulation disorders, heart and lung diseases, not taking contraceptives and aspirin before the operation
Exclusion criteria:
occurrence of uncontrollable allergic symptoms such as moderate to severe itching, or skin reactions such as skin rashes due to the consumption of caraway oil
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization The random allocation of patients to two groups is done by the permutation block stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of arrival. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2 . assimilation The two groups are matched in terms of age and gender using the permutation block stratified randomization method.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this research, single blinding method is used. So that the patient will not know the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Medical School - University of Medical Sciences Zahedan
Street address
Zahedan, Dr. Hasabi Square, University of Medical Sciences, Faculty of Medicine
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2022-07-24, 1401/05/02
Ethics committee reference number
IR.ZAUMS.REC.1402.032

Health conditions studied

1

Description of health condition studied
Edema and ecchymosis
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
Edema severity
Timepoint
The third day after the operation, the fifth day after the operation, the seventh day after the operation
Method of measurement
Physical and clinical assessment

2

Description
Severity of ecchymosis
Timepoint
The third day after the operation, the fifth day after the operation, the seventh day after the operation
Method of measurement
Physical and clinical assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group includes people who have undergone rhinoplasty surgery and after the surgery, a dropper containing 10 ml of corn oil is provided to the patients in the intervention group and it is recommended to the patients twice a day for up to seven days after the surgery. Using half a milliliter (10 drops) of oil, grease the upper part of the cheek and the bruised areas completely with Beneh oil prepared at Danesh Banyan Company approved by Zahedan University of Medical Sciences.

Category
Treatment - Other

2

Description
Control group: The control group includes people who have undergone rhinoplasty surgery and receive placebo after surgery. Liquid paraffin will be used as a placebo and it will be the same color as oil by food coloring. Kernel oil and paraffin packaging will be exactly the same. It is recommended that patients apply half a milliliter of placebo twice a day for seven days, prepared in Danesh Banyan company approved by Zahedan University of Medical Sciences.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Dashti's Otorhinolaryngology Clinic

Full name of responsible person
Gholamali Dashti Khovidaki

Street address
Zahedan, the beginning of Health St., Tawheed Intersection. Aramis doctors building

City
Zahedan

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Sistan-va-Balouchestan

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9816737789

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+98 935 102 3969

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DRDASHTI502@YAHOO.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Dr. Gholam Ali Dashti Khoiki

Street address
Zahedan - Shahid Motahari Blvd (Airport) - not reaching Khatam Square, Al Zahra Hospital

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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
Zahedan 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Fatemeh Sadat Hashemi Nesab

Position
Specialist assistant in Iranian medicine

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Zahedan - Doctor Hasabi Square - University of Medical Sciences campus

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hashemifa67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Gholamali Dashti Khovidaki

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Zahra sarani

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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 through published reports and articles will be.

When the data will become available and for how long
Access period 6 months after publication of results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Access to data with the permission of the person in charge of the study, only for scientific research is allowed

From where data/document is obtainable
Correspondence with the corresponding author via email

What processes are involved for a request to access data/document
Request from the person in charge of the study, one month after the request.

Comments