

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

Email address

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

Province

Sistan-va-Balouchestan

Postal code

9816737789

Phone

+98 935 102 3969

Email

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816737789

Phone

+98 935 102 3969

Email

DRDASHTI502@YAHOO.ac.ir

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 34 3211 0860

Email

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

Street address

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816737789

Phone

+98 935 102 3969

Email

DRDASHTI502@YAHOO.ac.ir

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

Street address

Dr. Hasabi Square, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816746557

Phone

+98 992 356 6382

Email

rahil19975@gmail.com.ir

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