

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of tea compress on the reduction of edema and ecchymosis in patients undergoing rhinoplasty after one week, which is tested unilaterally

Protocol summary

Study aim

The effect of tea compress on reducing edema and ecchymosis after rhinoplasty

Design

A concealed Clinical trial with control group, with two arm parallel groups on 75 patients with

Settings and conduct

Patients in the second half of 1400 in Firoozgar Hospital with rhinoplasty surgery, study duration one week. Patients' background information and the size of the ecchymosis, edema and pain will be recorded. Tea bags and packages containing cotton, which is similar to tea, are soaked by the patient in room temperature water for 15 minutes every three hours and placed on the cheeks for 10 minutes and taken daily. The patient does not know the content of the packs. On the seventh day, the patient is examined and the amount of pain reduction during the examination is recorded by the patient based on a score from 1 to 10. Finally, the evaluators are unaware of the content of each side and only the amount Edema and ecchymosis are expressed separately on each side Tea and cotton packs are pre-packaged in a shape and size that are exactly the same, unprocessed tea, such as cotton, has no color or odor.

Participants/Inclusion and exclusion criteria

Patients referred to a medical center for rhinoplasty surgery with the same treatment procedure without the use of any topical, oral or injectable drugs to reduce postoperative complications

Intervention groups

Evaluation of the effect of tea compress on the reduction of edema and ecchymosis in patients undergoing rhinoplasty, which is used unilaterally and on the opposite side, a sanitary pad without additives is used as a control group

Main outcome variables

Ecchymosis ; Edema ; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210726051994N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Pegah Foroughi Mobarakeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2229 0940

Email address

pegahforoughi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tea compress on the reduction of edema and ecchymosis in patients undergoing rhinoplasty after one week, which is tested unilaterally

Public title

Effect of tea compress on edema and ecchymosis after rhinoplasty after one week

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing rhinoplasty

Exclusion criteria:

Use topical or oral medication to reduce edema and ecchymosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

More than 1 sample in each individual

Number of samples in each individual: **2**

Use the pack on one side and the opposite side as a control

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

A certain number of packs prepared with the cooperation and approval of the Faculty of Pharmacy of the International Campus of the University of Iran, are given to the patient and in contrast, sanitary pads are used and the patient is not aware of the content of each. Which evaluators are unaware of the use of the packs and only determine the amount of edema and ecchymosis on each side.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No. 8 , 15, Mottaghian Ave , Farmanieh Blvd

City

Tehran

Province

Tehran

Postal code

193885432

Approval date

2020-09-23, 1399/07/02

Ethics committee reference number

IR.IUMS.FMD.REC.1399.402

Health conditions studied**1****Description of health condition studied**

Rhinoplasty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Changes in pre-orbital ecchymosis are measured based on a score of 0-4

Timepoint

During the week after the operation, daily at a specific time

Method of measurement

Based on score of 0_4 , zero: no ecchymosis, 1: involvement in the medial canthus and less than 1/4, 2: involvement to the pupil and between 1/4 to 1/2, 3: Involvement over the pupil and between 1/2 to 3/4, 4: Involvement reaches the lateral canthus

2**Description**

Eyelid edema changes based on a score of 0 to 4

Timepoint

During the week after the operation, daily at a specific time

Method of measurement

Based on a score of 0_4, zero: no edema, 1: involvement of a small amount of iris from above and below, 2: part of the iris is covered but does not reach the pupil 3: edema reaches the pupil and the iris is covered from above and below, 4 : The eyes are completely closed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The test drug used for treatment in this study was a tea-bag formulation of tea plant leaves powder. Each teabag contained 2.5g of the leaves powder. The dose given was one teabag five times a day, that is, every three hours, for seven days of treatment. A certain number of packs prepared with the cooperation and approval of the Faculty of Pharmacy of the International Campus of the University of Iran, given to the patient and placed in water at room temperature for 15 minutes, then topically for 10 minutes every three hours, from the first day after Surgery is used during waking hours on a specific side of the cheek and away from the surgical incision site.

Category

Treatment - Other

2

Description

Control group: A package containing cotton, which is similar to tea, will be given to patients in the required number. On the other hand, the contents of the pads are used without the patient's knowledge

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Educational Research Center, Iran
University of Medical Sciences and Health Services

Full name of responsible person

Pegah Foroughi Mobarakeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Pegah Foroughi Mobarakeh

Position

Otorhinolaryngology and Head and Neck Surgery
Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

The postoperative documentation, which in the present study is photographs, can be shared after unidentifying individuals. According to the evaluation form of edema and ecchymosis, which is the examination of the eyelids, there is no need to identify the nose and cheeks and only the eyelids are visible.

When the data will become available and for how long

Start of access period after data analysis.

To whom data/document is available

Accessibility for people working in the field of medicine.

Under which criteria data/document could be used

In case of using data or documents in other research and in the field of research.

From where data/document is obtainable

Send request to pegahforoughi@yahoo.com Responsible person: Pegah Foroughi Mobarakeh

What processes are involved for a request to access data/document

Sending a request for data via e-mail address and stating the reasons for the request as well as how and when to use it.

Comments