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
1938885432

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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No 8 , 15 , Mortaghian Ave , Farmanieh Blvd

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Phone
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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

Contact

Name of organization / entity

Iran University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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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