Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of Anaheal and oral Corticosteroids in reducing Edema and Ecchymosis after Rhinoplasty.

Protocol summary

Study aim

Comparison of the effect of Anaheal and oral corticosteroids in reducing edema and ecchymosis after rhinoplasty

Design

A randomized, blinded, clinical trial with tow parallel group design of 120 patient.

Settings and conduct

this study is performed in the offices and clinics of kermanshah dental school. 120 rhinoplasty applicants were randomly divided into two groups. In one group, Anaheal 500 is given daily, and in the second group, oral corticosteroids are given daily. the degree of ecchymosis and edema is calculated on a 4-point scale on the third, fifth, seventh days after surgery. the data is then analyzed. blinding is done with exactly the same drug packages that have secret codes related to the drug. patients and the executor of the project go blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: All clients requesting rhinoplasty surgery exclusion criteria: Underlying diseases Taking oral or injectable drugs from other medical centers History of allergy to corticosteroid

Intervention groups

In almost all patient with Rhinoplasty, edema and ecchymosis are seen as two expected outcomes of rhinoplasty. ecchymosis after surgery can be mild or severe, which depends on several factors, including the type and method of surgery and the patient's tendency to bruise. Postoperative edema is caused by an increase in interstitial fluid at the sit and can caused pain and, is severe, affect the final outcome of the surgery. Steroids reduce the permeability of the arteries and prevent exudate and blood from leaving the arteries. In this way, it prevents edema and ecchymosis. Anaheal is a combination of pineapple stem- derived protease enzymes that is used as an antiedema and antithrombotic and fibrinolytic properties.

Main outcome variables

primary consequence: The rate of edema and ecchymosis secondary consequence: does not have

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210805052086N1**
Registration date: **2021-11-04, 1400/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-04, 1400/08/13**
Update count: **0**

Registration date

2021-11-04, 1400/08/13

Registrant information

Name

Yavar Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of the effect of Anaheal and oral Corticosteroids in reducing Edema and Ecchymosis after Rhinoplasty.

Public title
Comparative study of the effect of Anaheal and oral Corticosteroids in reducing Edema and Ecchymosis after Rhinoplasty

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
All clients requesting rhinoplasty surgery
Exclusion criteria:
Underlying diseases such as hemophilia, asthma, and liver and kidney failure Taking oral or injectable drugs from other medical centers History of allergy to corticosteroid

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples studied in this study will be done using random assignment of patient to the study groups. In the study, samples are assigned to the two groups by permutation block random sampling. Thus, the study will continue until the number of samples is completed. In the method, we first determine a sample size of the general sample and then randomly assign a set of them to one group and the rest to another group. to the perform this randomization method, we proceed as follow: 1- The total sample size and the sample size ratio in the groups are determined. in the study, the number of samples will be 120 people with a 1:1 allocation. 2- The number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. 3- For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block of 0.5. block 0-4 can be used for the first group and block 5-9 for the second treatment. 4- Based on the selected numbers from the table of random numbers and determination of blocks, it is clear in which group each person who enters the study will be placed

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are treated with medication packages pre-determined by the study supervisor. drug packages are a quite similar in shape and patients are not aware of the contents of the packages. The cards with the number 1 and 2 on them and the secret codes related to the drug are in the packages and every patient who enters the study and receives the medicine dies not know the type of medicine. In addition, collecting information, assessing patients and completing forms is done by the project manager and his assistant, who are not aware of the contents of the packages; Therefore, the study is double-blind and the contents of the two drug groups are not clear from the stage of the patient entering the study until the end of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Shahid Beheshti Boulevard, Building No. 2 of Medical Sciences, Research and Technology Department

City
Kermanshah

Province
Kermanshah

Postal code
671463159

Approval date
2021-10-19, 1400/07/27

Ethics committee reference number
IR.KUMS.REC.1400.531

Health conditions studied

1

Description of health condition studied
Rhinoplasty

ICD-10 code
Z41

ICD-10 code description
Encounter for procedures for purposes other than remedying health state

Primary outcomes

1

Description
The rate of edema
Timepoint
Third, fifth and seventh day
Method of measurement
4-point scale

2

Description
The rate of ecchymosis
Timepoint
Third, fifth and seventh day
Method of measurement
4-point scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Take Anaheal 500mg oral tablets twice a day; morning and night, for 7 days
Category
Treatment - Drugs

2

Description
Intervention group: Take prednisolone 5 mg oral tablets twice a day; morning and night, for 7 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sajjad Hospital
Full name of responsible person
Farzad Rezai
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology
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
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Full name of responsible person
Farzad Rezai
Position
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available