

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

+98 83 4652 3190

##### Email address

yavarsayadi@yahoo.com

##### 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 does 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

##### Street address

Kermanshah, Bahar St., Sajjad Hospital

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6717880167

##### Phone

+98 83 3725 3607

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Reza Khodarahmi

##### Street address

Deputy of Research and Technology, Building No.2, Shahid Beheshti Blvd.

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##### Province

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##### Postal code

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##### Phone

+98 83 3838 4185

##### Email

reseaech\_it@kums.ac.ir

#### 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Farzad Rezai

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

School of Dentistry, Shura St.

##### City

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##### Province

Kermanshah

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Yavar Sayadi  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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Pardis Town  
**City**  
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**Province**  
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**Postal code**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
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Yavar Sayadi

**Position**  
student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Unit 1, 10th floor, E11 Block, Shaghayegh Blvd.,  
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**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6717880167  
**Phone**  
0098 83 6523190  
**Email**  
yavarsayadi@yahoo.com

## 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