

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Investigation the effect of tranexamic acid on reduction of edema and ecchymosis in patients undergoing rhinoplasty

Protocol summary

Study aim

Investigation the effect of tranexamic acid on reduction of edema and ecchymosis in patients undergoing rhinoplasty

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 120 patients candidate for rhinoplasty.

Settings and conduct

This study will be conducted with the aim of investigation the effect of tranexamic acid on edema and ecchymosis reduction in 120 patients candidate for rhinoplasty. After inclusion in the study, using block randomization with quadrilateral blocks method the patients will be assigned into two groups; tranexamic acid group receiving 1000 mg tranexamic acid 2 hours before operation and 1000 mg every 8 hours after operation for 3 times and control group receiving placebo. Finally, 3, 5, 7 and 10 days after surgery the edema and ecchymosis will be measured using 0-4 Point scoring tool and will be compared together.

Participants/Inclusion and exclusion criteria

Inclusion criterion: patients candidate for rhinoplasty
Exclusion criteria: Allergy to tranexamic acid, having coagulation disorders, having a history of gastric ulcer or bleeding

Intervention groups

Intervention group: Receiving 1000 mg tranexamic acid 2 hours before operation and 1000 mg every 8 hours after operation for 3 times
Control group: Receiving tranexamic acid placebo 2 hours before operation and every 8 hours after operation for 3 times

Main outcome variables

Edema Ecchymosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046095N1**

Registration date: **2020-05-30, 1399/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-30, 1399/03/10**

Update count: **0**

Registration date

2020-05-30, 1399/03/10

Registrant information

Name

Hanie Samareh khammar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3348 9551

Email address

hani.samareh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of tranexamic acid on reduction of edema and ecchymosis in patients undergoing rhinoplasty

Public title

The effect of tranexamic acid on reduction of edema and ecchymosis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients candidate for rhinoplasty

Exclusion criteria:

Allergy to tranexamic acid Having coagulation disorders
Having a history of gastric ulcer or bleeding

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 10. The patients will be randomly assigned into 2 groups of 60. Considering the sample size of 120 (60 patients in tranexamic acid group and 60 patients in placebo group) , 12 blocks with 10 people will be selected; in each block there will be 5 cards of each group. So by selecting each block, 5 people will be assigned into each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Tranexamic acid drugs and placebo boxes have a similar appearance so the patients are blinded (When giving a written consent, it will be explained to the patients that for improving the accuracy of the results, the patients should be blinded but they are either in tranexamic acid or placebo group. The cons and pros of each treatment option will be explained). Assignment of the patients into two groups will be done by the student (researcher) and the surgeon who will also evaluate the patients after surgery for the edema and ecchymosis won't be aware of the assignment so he is blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ZAUMS.REC.1397.065

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**

Edema

Timepoint

On post-operative days 3, 5, 7 and 10

Method of measurement

0-4 Point scoring tool

2**Description**

Ecchymosis

Timepoint

On post-operative days 3, 5, 7 and 10

Method of measurement

0-4 Point scoring tool

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving 1000 mg tranexamic acid 2 hours before operation and 1000 mg every 8 hours after operation for 3 times

Category

Prevention

2**Description**

Control group: Receiving tranexamic acid placebo 2 hours before operation and every 8 hours after operation for 3 times

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam al Anbiya Hospital

Full name of responsible person

Hanie Samareh Khammar

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Phone

+98 54 3329 5715

Email

hani.samareh@zaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5721

Email

Dr.Taheri@zaums.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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Hanie Samareh khammar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Phone

+98 54 3348 9551

Fax**Email**

hani.samareh@zaums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Hanie Samareh khammar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Phone

+98 54 3348 9551

Fax

Email

hani.samareh@zaums.ac.ir

Postal code

9916789547

Phone

+98 54 3348 9551

Fax

Email

hani.samareh@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hanie Samareh khammar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable