Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Samare 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

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Person responsible for updating data

Contact

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Fax

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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

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