

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of local effect of tranexamic acid and phenylephrine on bleeding rate in rhinoplasty

Protocol summary

Study aim

Determining the comparison of the local effect of tranexamic acid and phenylephrine on the rate of bleeding in rhinoplasty in patients undergoing rhinoplasty in Shahid Ayatollah Dastgheib Hospital in Shiraz, 2019-2020

Design

study was performed on 98 patients in Ayatollah Dastgheib Hospital on rhinoplasty candidates who were randomly admitted to the study. Randomization is performed in a one-to-one ratio between the two groups in variable block sizes. The subjects were divided into two study groups. Website address: <https://www.randomizer.org/>

Settings and conduct

This study was performed on 98 patients in Dastgheib Hospital in Shiraz who in two intervention groups poured 1 cc of phenylephrine and tranexamic acid on the mesh and packed for five minutes immediately after intubation and before making a surgical incision inside the nasal cavity.

Participants/Inclusion and exclusion criteria

Entry requirements: Candidate patients for rhinoplasty, willingness to participate in the intervention full consciousness, age 20-30 years Exit conditions: Sensitivity known to tranexamic acid and phenylephrine Tachycardia and high blood pressure 140/90 History of coagulation disorder, warfarin use.

Intervention groups

Intervention group with 1 cc of phenylephrine (Phenylephrine Hcl, Nasal Drop, 0.5%) which is poured on the mesh and packed for five minutes immediately after intubation and before making a surgical incision inside the nasal cavity. In the second group, 1 cc of tranexamic acid (Solution 500mg / 5ml) is used in the same way.

Main outcome variables

Blood pressure, tachycardia, bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201205049602N1**

Registration date: **2021-04-24, 1400/02/04**

Registration timing: **retrospective**

Last update: **2021-04-24, 1400/02/04**

Update count: **0**

Registration date

2021-04-24, 1400/02/04

Registrant information

Name

Negar Shahkarami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3222 0639

Email address

negar.shahkarami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-06, 1399/09/16

Expected recruitment end date

2021-01-05, 1399/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of local effect of tranexamic acid and phenylephrine on bleeding rate in rhinoplasty		physician and the outcome assessor are not aware of the assignment of the subjects to the study groups.	
Public title	Comparison of the effect of tranexamic acid and phenylephrine on bleeding rate in rhinoplasty	Placebo	Not used
Purpose	Supportive	Assignment	Parallel
Inclusion/Exclusion criteria		Other design features	
Inclusion criteria:	Candidate patients for rhinoplasty willingness to participate in the intervention full consciousness age 20-30 years	Secondary Ids	empty
Exclusion criteria:	Sensitivity known to tranexamic acid and phenylephrine Tachycardia and high blood pressure140/90 History of coagulation disorder, warfarin use Sensitivity known to tranexamic acid high blood pressure140/90 History of warfarin use	Ethics committees	
Age	From 20 years old to 30 years old	1	
Gender	Both	Ethics committee	
Phase	3	Name of ethics committee	Ethics Committee of Mazandaran University of Medical Sciences
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser	Street address	Farah abad,Mazandaran University of Medical Sciences
Sample size	Target sample size: 98	City	Sari
Randomization (investigator's opinion)	Randomized	Province	Mazandaran
Randomization description	Individuals are assigned a login number in the order they enter. This number is also used for all their data collection forms. The randomization sequence is generated by an epidemiologist based on randomizer software. Randomization is first divided into two categories based on the name of the surgeon (two surgeons). Then, in each of these two classes, randomization is performed in a one-to-one ratio in variable block sizes (multiples of 2). Based on this, people are assigned to one of the two groups studied. The numbers are based on the order in which people enter the study. From 1 to 98. These numbers are written on the back of the envelopes and inside the code envelope specified by the randomizer software. In order, after entering each person with the eligibility criteria, the first envelope is opened and based on the specified code, the drug with the same code written on the label is injected into the person. Website address of randomizer software: https://www.randomizer.org/	Postal code	7195865364
Blinding (investigator's opinion)	Double blinded	Approval date	2020-08-11, 1399/05/21
Blinding description	The patient is anesthetized and is not aware of his affiliation with any of the study groups. Mesh preparation with phenylephrine and tranexamic acid content is performed by an independent colleague and the	Ethics committee reference number	IR.MAZUMS.REC.1399.518
		Health conditions studied	
		1	
		Description of health condition studied	Rhinoplasty
		ICD-10 code	M95.0
		ICD-10 code description	Acquired deformity of nose
		Primary outcomes	
		1	
		Description	Bleeding
		Timepoint	Before the intervention, 5, 15 and 30 minutes after the intervention
		Method of measurement	Calculation of the amount of blood in the suction and the surgeon's satisfaction with the surgical field
		2	
		Description	Tachycardia

Timepoint

Before the intervention, 5, 15 and 30 minutes after the intervention

Method of measurement

Using patient vital signs monitoring

3**Description**

blood pressure

Timepoint

Before the intervention, 5, 15 and 30 minutes after the intervention

Method of measurement

Using patient vital signs monitoring

Secondary outcomes

empty

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

Intervention group: In the first group, 1 cc of phenylephrine (Phenylephrine Hcl, Nasal Drop, 0.5%) is drawn with a syringe and poured on the mesh and packed for five minutes immediately after intubation and before making a surgical incision inside the nasal cavity.

Category

Prevention

2**Description**

Intervention group: In the second group, 1 cc of solution for injection Tranexamic Acid, Injection Solution 500mg / 5ml,) with a syringe and poured on the mesh and packed for five minutes immediately after intubation and before making a surgical incision inside the nasal cavity
Be

Category

Prevention

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

Shahid Ayatollah Dastgheib Hospital in Shiraz

Full name of responsible person

Hooshang Akbari

Street address

Hafez Ave

City

Shiraz

Province

Fars

Postal code

7195865364

Phone

+98 71 3222 0630

Email

negar.shahkarami@yahoo.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

Majeed saeedi

Street address

NO. 140, Amir Mazandarani Ave, Keshavarz Blv

City

Sari

Province

Mazandaran

Postal code

719565364

Phone

+98 71 3222 0639

Email

negar.shahkarami@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Negar shahkarmi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

NO, 12. Mirza Hafez Ave

City

SHiraz

Province
Fars
Postal code
7195865364
Phone
+98 71 3222 0639
Email
negar.shahkarami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hooshang Akbari
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Farah Abad Ave, Mazandaran University of Medical Sciences
City
Sari
Province
Mazandaran
Postal code
8137946855
Phone
+98 11 3304 4000
Email
hooshangakbari@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Negar shahkarami
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Others
Street address
No,12. Mirza Hafez Ave
City
Shiraz
Province
Fars
Postal code
715865364
Phone
+98 71 3222 0639
Email
negar.shahkarami@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