

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Efficacy of Tranexamic Acid and the Association of Rate Pressure Product Index on Intraoperative Bleeding during Rhinoplasty.

#### Protocol summary

##### Study aim

The Efficacy of Tranexamic Acid and the Association of Rate Pressure Product Index on Intraoperative Bleeding during Rhinoplasty.

##### Design

Double-blind placebo-controlled clinical trial

##### Settings and conduct

Intervention group: patients received 1gr Tranexamic acid intraoperatively (total volume of 10 cc). Control group: patients received the same volume of Tranexamic acid (10 cc) of normal saline as placebo intraoperatively in the second group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18-45 year\_ old patients undergoing rhinoplasty surgery. Exclusion Criteria: patients with systemic disease, history of any drug consumption, hemorrhagic disease, liver dysfunction, renal dysfunction, using anticoagulant drugs, heart block, myocardial ischemia and morbid obesity.

##### Intervention groups

Intervention group: patients received 1gr Tranexamic acid intraoperatively (total volume of 10 cc). Control group: patients received the same volume of Tranexamic acid (10 cc) of normal saline as placebo intraoperatively in the second group.

##### Main outcome variables

Intra and postoperative bleeding, The rate-pressure product (RPP), Blood pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N109**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**

Update count: **0**

##### Registration date

2021-02-08, 1399/11/20

##### Registrant information

###### Name

Farzaneh Masihi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3647 4270

###### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-17, 1399/11/29

##### Expected recruitment end date

2021-03-04, 1399/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Efficacy of Tranexamic Acid and the Association of Rate Pressure Product Index on Intraoperative Bleeding during Rhinoplasty.

##### Public title

The Efficacy of Tranexamic Acid and the Association of Rate Pressure Product Index on Intraoperative Bleeding during Rhinoplasty.

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

18-45 year\_ old patients undergoing rhinoplasty surgery.

### **Exclusion criteria:**

Patients with systemic disease History of any drug consumption Hemorrhagic disease Liver dysfunction Renal dysfunction Using anticoagulant drugs Heart block Myocardial ischemia Morbid obesity

## **Age**

From **18 years** old to **45 years** old

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **86**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Computer-generated randomization table will be used to randomly allocated patients to the intervention and placebo groups based on www.sealedenvelope.com Seed: 258004702634303 block sizes 4,6 and 8.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

Medications were prepared by other nurses who were totally unaware of the nature of the study. While anesthesiologist and surgeon were blinded, Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs used in the study.

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7134844119

##### **Approval date**

2019-01-13, 1397/10/23

##### **Ethics committee reference number**

IR.SUMS.MED.REC.1397.457

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Rhinoplasty surgery

#### **ICD-10 code**

Z41.1

#### **ICD-10 code description**

Encounter for cosmetic surgery

## **Primary outcomes**

### 1

#### **Description**

Intra and postoperative bleeding

#### **Timepoint**

Intra-operatively

#### **Method of measurement**

Weighing surgical gauzes using a digital scale

### 2

#### **Description**

The rate-pressure product (RPP)

#### **Timepoint**

Every 10 min

#### **Method of measurement**

Formula: heart rate multiply systolic arterial pressure

## **Secondary outcomes**

### 1

#### **Description**

Blood pressure

#### **Timepoint**

In the recovery room for the first 6

#### **Method of measurement**

Noninvasive blood pressure monitoring

## **Intervention groups**

### 1

#### **Description**

Intervention group: patients received 1gr Tranexamic acid intraoperatively (total volume of 10 cc)

#### **Category**

Prevention

## 2

### Description

Control group: patients received the same volume of Tranexamic acid (10 cc) of normal saline as placebo intraoperatively in the second group.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khalili Hospital

##### Full name of responsible person

Forogh Moradi

##### Street address

Khalili St, Khalili Educational and Medical Center

##### City

Shiraz

##### Province

Fars

##### Postal code

1433671348

##### Phone

+98 71 3629 1470

##### Email

khalili@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaieanzadeh

##### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

vcrd@sums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Forogh Moradi

##### Position

Anesthesiology Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

forooghmoradi.fm.67@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mehrdad Salari

##### Position

Anesthesiologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

**Email**

msalari@sums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

BS in anesthesia/English Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Namazi Hospital, Namazi square

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3647 4270

**Email**

masihifarzaneh@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Its against our center polices.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available