# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

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+98 71 3647 4270

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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
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## Sponsors / Funding sources

**1**

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Shiraz University of Medical Sciences
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**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
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Forogh Moradi
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Anesthesiology Resident
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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