

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison the efficacy of Tranexamic acid in intervention and placebo groups in rhinoplasty patients

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effectiveness of tranexamic acid in intraoperative bleeding and post operative edema and echymosis. This study is a double-blinded clinical trial on 60 rhinoplasty candidates with no systemic problem. The subjects will be randomly divided into two groups. The first group (control) will receive routine treatment. In the second group (target group) in addition to routine treatment, 10 mg/kg tranexamic acid intravenously just before surgery will be administered. The amount of bleeding during the surgery will be measured by suctioned fluids, bloody and dry gas weight difference. Eyelid edema and ecchymosis around the eyes will be measured using standard scoring tools 24 hours after surgery by an observer. The results obtained will be statistically analyzed and the significance will be examined to determine the effect of tranexamic acid.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013071013938N1**  
Registration date: **2014-07-12, 1393/04/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-12, 1393/04/21

##### Registrant information

##### Name

Mohamadali Ghavimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 5968

##### Email address

ghavimim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-08-22, 1392/05/31

##### Expected recruitment end date

2014-08-22, 1393/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the efficacy of Tranexamic acid in intervention and placebo groups in rhinoplasty patients

##### Public title

The effect of Tranexamic acid in bleeding and echymosis in corrective nose surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Healthy Men and Female; Age range between 19- 39. Exclusion criteria: Men and Female between 19- 39 years old with Systemic and Methabolic diseases.

##### Age

From **19 years** old to **39 years** old

##### Gender

Both

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Central Bulding of Tabriz University of Medical Sciences, Golgasht st, Azadi ave

##### City

Tabariz

##### Postal code

#### Approval date

2014-05-26, 1393/03/05

#### Ethics committee reference number

9332

## Health conditions studied

### 1

#### Description of health condition studied

Bleeding ,Oedema and Echymosis

#### ICD-10 code

Y40,Y84

#### ICD-10 code description

Anaesthetics and therapeutic gases

## Primary outcomes

### 1

#### Description

Bleeding

#### Timepoint

Just after intervention

#### Method of measurement

$x = \text{volum of suction} + (\text{weight of bloody guazes} - \text{weight of dry guazes})$  total bleeding =  $x - \text{volum of irigation fluides}$  uses in surgery

## Secondary outcomes

### 1

#### Description

Oedema

#### Timepoint

24 hours after surgery

#### Method of measurement

Standarad 4 scale system

### 2

#### Description

Echymosis

#### Timepoint

24 hours after surgery

#### Method of measurement

Standarad 4 scale system

## Intervention groups

### 1

#### Description

IV administration of 10 mg/kg tranexamic acid just before beginning of surgery

#### Category

Treatment - Drugs

### 2

#### Description

20 ml normal saline IV injection as placebo

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emamreza hospital

##### Full name of responsible person

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr.farhoodi

##### Street address

Building no 2, Tabriz Univercity of Medical Sciences, Golgasht st

##### City

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Ghavimi

**Position**

Assistant Professor of Oral and Maxillofacial Surgery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Miramir Chavoshzadeh

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Dentistry student

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*