

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of the prophylactic dose of Tranexamic acid on the amount of bleeding in jaw surgeries :a prospective randomized double blind clinical trial study

#### Protocol summary

##### Summary

various techniques are used to achieve the ideal operative field necessary for successful jaw surgeries and decreased bleeding. Controlled hypotension is one way that used to improve surgical conditions during jaw surgery .Tranexamic acid is another way which allow control of intraoperative bleeding and thus might be valuable tool to compare with other techniques .The aim of this study is the compare of the surgical field , intraoperative bleeding in patients in whom Tranexamic acid is used as apposed to placebo.For this reason in a double blind randomized clinical trial 90 patients from 18 to 40 years old,ASA class I or II that scheduled for compound jaw fractures surgery will select (after explaining the process of the trial, written informed consent obtained from participants) .Patients with coagulation disorders ,head injury or drug sensitivity will be excluded from this study .anesthesia technique is similar in both of groups. Then they will divide into two groups randomly, the first group will receive intra venous Tranexamic acid 10 mg/kg , second group normal saline with the same volume and surgical condition and intraoperative bleeding ,post operative hematocrite after 6 hours will be recorded and then analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060115963N2**

Registration date: **2014-06-29, 1393/04/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-06-29, 1393/04/08

#### Registrant information

##### Name

Soudabeh Haddadi

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13332383068

##### Email address

so\_haddadi@gums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Guilan University of Medical Sciences, Research Vice

#### Expected recruitment start date

2014-05-05, 1393/02/15

#### Expected recruitment end date

2014-11-21, 1393/08/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Efficacy of the prophylactic dose of Tranexamic acid on the amount of bleeding in jaw surgeries :a prospective randomized double blind clinical trial study

#### Public title

anesthesia technique in jaw surgeries

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for jaw fractures surgery (18-40yr); ASA class I, II Exclusion criteria:

History of Hemorrhagic Disease; thrombosis; Drugs That affect on the surgical Homeostasis; Anemia (Hematocrite <30);history of head injury ;intra cranial hematoma ; drug sensitivity to Tranexamic acid

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### 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

Guilan University of Medical Sciences Research Vice

##### Street address

Dr Beheshti st.

##### City

Rasht

##### Postal code

#### Approval date

2014-05-05, 1393/02/15

#### Ethics committee reference number

1930069507

## Health conditions studied

### 1

#### Description of health condition studied

Dentofacial anomaly, unspecified

#### ICD-10 code

k07.9

#### ICD-10 code description

Dentofacial anomaly, unspecified

## Primary outcomes

### 1

#### Description

the amount of intra operative bleeding

#### Timepoint

Every 15 minutes

#### Method of measurement

in the base of the bloody gauzes , amount of blood in suction bottle

## Secondary outcomes

### 1

#### Description

surgical field condition

#### Timepoint

every 15 minutes

#### Method of measurement

in base on the table

## Intervention groups

### 1

#### Description

intervention-intra venous tranexamic acid 10 mg/kg  
placebo-normal saline

#### Category

Treatment - Drugs

### 2

#### Description

intervention - tranexamic acid 10 mg/kg iv placebo-normal saline

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Velayat hospital

##### Full name of responsible person

Dr Soudabeh Haddadi

##### Street address

Namjou st

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Guilan University of Medical Sciences Research Vice

##### Full name of responsible person

Susan Komaii

**Street address**

Dr Beheshti bl

**City**

Rasht

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

Yes

**Title of funding source**

Guilan University of Medical Sciences Research Vice

**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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Soudabeh Haddadi

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

Amiralmomenin Hospital

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**Postal code****Phone**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

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**Web page address****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*