

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of The Effect of The Tranexamic Acid and Placebo on The Amount of Bleeding in Patients Under Surgical Treatment of Bilateral Mandibular Fractures

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is evaluation of the effect of the tranexamic acid on the amount of bleeding in patients under surgical treatment of bilateral mandibular fractures. Total of sample size is 36 patients with ages: 20-40 years old. Patients with bilateral mandibular fractures are candidates for inclusion. The patients with unilateral mandibular fractures and cheekbone and maxillary fractures with subarachnoid hemorrhage will be excluded. The patients are randomly divided into two groups. The patients do not know what do they have received and evaluation of patients is performed by person who does not know about the protocol of the study. First group receives 20 ml of tranexamic acid (20mg/kg) before surgery. Second group receives 20 ml of normal saline solution (0.9%) before surgery. The amount of hemoglobin and hematocrit levels in patients is recorded before and after surgery in both groups by sampling blood. The amount of blood loss is calculated with subtracting preoperative and postoperative hemoglobin and hematocrit levels in blood. Patients do not use any medications before surgery. The temperature and the amount of body fluids can be controlled precisely by the anesthesiologist. All of patients undergoing surgery will be placed in the supine position (15 °).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051122204N1**
Registration date: **2015-06-10, 1394/03/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-10, 1394/03/20

Registrant information

Name

Majid Ahmadfar

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effect of The Tranexamic Acid and Placebo on The Amount of Bleeding in Patients Under Surgical Treatment of Bilateral Mandibular Fractures

Public title

The Effect of The Tranexamic Acid on The Amount of

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients undergoing bilateral mandibular fractures surgery. Exclusion Criteria: Patients with subarachnoid hemorrhage; History of CVA (cerebrovascular accident definition); History of thrombosis; History of renal diseases and hematuria; Patients with bone disease; Patients with cleft lip and palate; Patients with craniofacial syndromes; History of Temporomandibular joint surgery; History of bone transplant recipient.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The table of random numbers used for randomization, A code will be assigned to each patient by a person who does not know about the protocol of the study. Blood volume (BV)= 70 ml/kg for men and Blood volume (BV)= 65 ml/kg for women. CBL= Calculated blood loss

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2014-10-04, 1393/07/12

Ethics committee reference number

ajums.REC.1393.213

Health conditions studied

1

Description of health condition studied

Intraoperative bleeding

ICD-10 code

Y60

ICD-10 code description

Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care

Primary outcomes

1

Description

The amount of hemoglobin

Timepoint

Immediately before surgery and immediately after surgery

Method of measurement

Venous sampling and sent to the laboratory

2

Description

The amount of hematocrit

Timepoint

Immediately before surgery and immediately after surgery

Method of measurement

Venous sampling and sent to the laboratory

Secondary outcomes

1

Description

Bleeding (By calculating the difference between pre- and postoperative hemoglobin(Hb))

Timepoint

After surgery

Method of measurement

Using the formula: $CBL = BV \times (Hb \text{ loss} / Hb \text{ per})$, $Hb \text{ loss} = Hb \text{ pre} - Hb \text{ post} + t$ (The number of injected packed red blood cell units)

2

Description

Bleeding (By calculating the difference between pre- and postoperative hematocrit(Hct))

Timepoint

After surgery

Method of measurement

Using the formula: $CBL = RBCL / [(HCT_{per} + HCT_{post}) / 2]$, $RBCL = BV \times (Hct \text{ pre} - Hct \text{ post}) + 320 t$

Intervention groups

1

Description

Group I: injection of 20 ml of tranexamic acid (20 mg/kg), precisely before surgery

Category

Prevention

2

Description

Group II: injection of 20 ml of normal saline solution (0.9%), precisely before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mohamadreza Gousheh

Street address

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

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Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor For Research Of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Majid Ahmadfar

Position

Resident Oral and Maxillofacial Surgery

Other areas of specialty/work

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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