Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 hematochrite 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
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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 c lass I, II Exclusion criteria:

History of Hemorrhagic Disease; thrombosis; Drugs That affect on the surgical Homeostasis; Anemia (Hematochrite <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
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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
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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
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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