Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effect of preoperative oral tranexamic acid on intraoperative bleeding during rhinoplasty: A Clinical Trial

Protocol summary

Summary

(1) Objectives: Rhinoplastic surgery is one of the biggest challenges with manipulation or surgery to improve the cosmetic and functional nasal form. Tranexamic acid, is a competitive inhibitor of plasminogen activator in much higher concentrations is a non- competitive inhibitor of plasmin. In rhinoplastic surgery the amount of blood loss during surgery can be controlled in different ways, including the implementation of intraoperative controlled hypotension as well as the use of anti-fibrinolytic drugs such as tranexamic acid before, during, or after operation. Intraveneous tranexamic acid during surgical procedures are used. So far, studies on the use of pre-operative oral tranexamic acid on bleeding during rhinoplastic surgery hasn't been performed in adults. (2) Design: This study is a randomized, double-blind clinical trial study to evaluate the effects of preoperative oral tranexamic acid in adults candidated for rhinoplastic surgery for reducing blood loss in Shiraz Chamran Hospital. A total of 50 adult patients between the ages of 16 to 40 years were randomized to receive either oral tanexamic acid group and the placebo group assigned anesthesiologist, while the doctor, a student of project manager, will be unaware. After obtaining informed consent from the patient, 2 hours before surgery, by maxillofacial ward nurse's a 1,000 mg (two 500 mg tranexamic acid tablets orally) with about 20 cc of water 2 hours before surgery. (3) Setting and conduct: A questionnaire that included demographic information (age , sex and weight) - Medical History - Hemodynamic values recorded before, during and after operation, duration of surgery and the amount of intraoperative bleeding will be recorded. Bleeding with surgical weight Gauzes is calculated using a digital scale in the operating room, so that bloody Gauzes secured with Beex box to prevent evaporation. At the end of the operation is determined by the amount of blood in the suction device that is added to the total amount of intraoperative bleeding. (4) Participants including major eligibility criteria: The patients with systemic disease and no history of drug use, and willingness to cooperate in this study are enrolled: Exclusion criteria included known allergy to the study drug, hepatic and renal dysfunction and lack of signed informed consent will be excluded. (5) Intervention: Drug is administered with dose of 1000 mg (two 500 mg tablets) orally with about 20 cc of water are given to the patient's study 2 hours before surgery and the second group received placebo with about 20 cc of water patients. (6) Main outcome measures: Hemodynamic values is recorded before, during and post-operative and amount of blood loss during surgery as well as surgical duration, the weight of Gauze is calculated using a digital scale in the operating room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312271674N10**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source
Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Expected recruitment start date
2014-03-21, 1393/01/01

Expected recruitment end date
2015-01-20, 1393/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of preoperative oral tranexamic acid on intraoperative bleeding during rhinoplasty: A Clinical Trial

Public title
Is oral tranexamic acid effective in reduction of blood loss during rhinoplasty?

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria included: The patients with systemic disease and no history of drug use, and willingness to cooperate in this study are enrolled; Exclusion criteria included known allergy to the study drug, hepatic and renal dysfunction and lack of signed informed consent will be excluded.

Age
From **16 years** old to **40 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Ethics committee Of Shiraz University Of Medical Sciences

Street address
Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz

City
Shiraz

Postal code
1978-71345

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
CT-P-9368-6578

Health conditions studied

1

Description of health condition studied
Rhinoplasty

ICD-10 code
00

ICD-10 code description
00

Primary outcomes

1

Description
The amount of intraoperative bleeding

Timepoint
End of surgery

Method of measurement
Weight of the Gauze in the operating room for surgery with digital scale

2

Description
Blood pressure and heart rate values

Timepoint
Preoperative, intraoperative and postoperative

Method of measurement
Vital signs monitoring device

Secondary outcomes

1

Description
Side effects of postoperative oral tranexamic acid

Timepoint
Postoperative in recovery room

Method of measurement
The nurse reported in the recovery

2

Description
Agitation and postoperative shivering
Timepoint
Recovery room
Method of measurement
The nurse reported in the recovery

Intervention groups

1

Description
Drug is administered with dose of 1000 mg (two 500 mg tablets) orally with about 20 cc of water are given to the patient's study 2 hours before surgery.
Category
Treatment - Drugs

2

Description
The second group or control group received placebo with about 20 cc of water 2 hours before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Chamran Hospital
Full name of responsible person
Hamid Reza Eftekharian
Street address
Shiraz University Of Medical Sciences, Shiraz Chamran Hospital, Chamran Blvd., Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences
Full name of responsible person
Gholam Reza Hatam
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Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz
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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
Vice-Chancellery of Research and Technology, Shiraz 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

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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