

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy of Tranexamic Acid on Blood Loss During Rhinoplasty

Protocol summary

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Study aim

Evaluating the efficacy of Tranexamic Acid on bleeding during rhinoplasty

Design

Randomized, parallel group, placebo-controlled, double-blinded clinical trial

Settings and conduct

Kashani Hospital in Shahrekord, Iran

Participants/Inclusion and exclusion criteria

18- to 60-year-old healthy patients candidate for rhinoplasty

Intervention groups

Administration of Tranexamic Acid in intervention group, Administration of Placebo in control group

Main outcome variables

Hemoglobin concentration/Blood volume in suction

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Tranexamic Acid on Blood Loss During Rhinoplasty

Public title

Efficacy of Tranexamic Acid on Blood Loss During Rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Without any systemic disease ASA I category

Exclusion criteria:

Drug abuser or addict Renal or Liver failure Hemostatic disorders History of convulsion Hypersensitivity to Tranexamic Acid Pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008458N2**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Sanaz Ziaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 0106

Email address

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using google's online coin flipper. First, each group will be assigned to a coin flip result. Thereafter, a coin flip will be performed using google's online coin flipper, for each individual, and it will be decided whether the participant is in the Case or Control group. This process will be performed by one of the health care providers before the surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not know whether they participate in the Case or Control group. Apart from being informed about their participation in a clinical trial, they will receive no further information on the details of the interventions and also, they will be unconscious at the time of the random allocations. Inevitably, some healthcare providers will be informed of the details of the interventions, however, they will be instructed not to give out these information to any other person, except the data gatherer after gathering all of the data, or in case of a possible related emergency. It is worth to mention that the surgeon and the researchers will not be aware of the contents of the administered syringes. The Data Safety and Monitoring Board will only be informed of these details in case of a possible related necessity. The data gatherer will not be informed whether each patient is in the Case or Control group, until after the gathering of all the data. Thereafter, the data gatherer will be informed with the details of the interventions, and will enter all of the gathered information in the SPSS software. Participants will then be assigned with identifiers, generated with an online number generator software (numbergenerator.org). Therefore, the principle investigator, outcome assessors, and the manuscript writers will be blind to the identity of participants in both Case and Control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sharekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences,
Rahmatiye Ave., Shahrekord, Iran.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.SKUMS.REC.1398.079

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Amount of bleeding

Timepoint

Before intervention, Immediately after intervention

Method of measurement

Hemoglobin concentration and blood volume in suction

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving Tranexamic Acid (Tranexip, Caspian Tamin Pharmaceutical) 10mg/kg IV right before surgery, and after induction of anesthesia

Category

Treatment - Drugs

2

Description

Control group: Patients receiving placebo (normal saline) in equal volumes with the case group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital
Full name of responsible person
Hesam Panahi
Street address
Parastar Ave.
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Postal code
8813833435
Phone
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Email
Hesam_panahi_87@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Lotfollah Afzali
Street address
Parastar Ave.
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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
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person

Hesam Panahi
Position
Resident Doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

Contact

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Efficacy of Tranexamic Acid on bleeding during rhinoplasty

When the data will become available and for how long

Not decided

To whom data/document is available

Identified Researchers

Under which criteria data/document could be used

Not specified

From where data/document is obtainable

Not decided

What processes are involved for a request to access data/document

Not decided

Comments