Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of intravenous tranexamic acid on bleeding during burn surgery: a double blinded clinical trial

Protocol summary

Study aim

Our aim was to investigate and measure the effect of intravenous injection of tranexamic acid on bleeding during burn surgery in patients with severe burns during a double-blind clinical trial.

Design

A clinical trial with parallel, double-blind groups, randomized, phase 4 on 82 patients. For randomization, the Rnnif command of software R is used.

Settings and conduct

In a burn OR, severe burn patients receive tranexamic acid and a placebo solution in separate groups before anesthesia. The volume of bleeding is calculated by hemoglobin before and after surgery, volume of bleeding, and transfusion. Burn surgeon, patients, and the resident in charge of data registration are blinded to the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-50 years, severe burns, and candidates for burn surgery. Exclusion Criteria: history of cardiovascular disease, liver or kidney damage, pregnancy or lactation, ophthalmic pathologies, different coagulopathies, or history of allergy to tranexamic acid, drug side effects such as seizures and vascular thromboembolic events.

Intervention groups

In the α group (standard treatment) before induction of anesthesia, 10mg/kg of normal saline solution will be infused into the patient Intravenously and continued every hour during surgery. The above is to protect the blinding. In the β group (receiving 10mg/kg Tranexamic acid) before induction of anesthesia, 10mg/kg of Tranexamic solution in normal saline serum will be infused for 5 minutes. The patient will be anesthetized under the supervision of an anesthesiologist. Then, from the onset of surgery to the end of the surgery, 1mg/kg of the same substance will be infused into the serum every hour.

Main outcome variables

The volume of bleeding during surgery: blood in the suction device, the number of blood gases, the amount of blood in the field of surgery, the Gross formula.

General information

Reason for update

Acronym

TXA

IRCT registration information

IRCT registration number: **IRCT20210524051384N8**
Registration date: **2022-10-25, 1401/08/03**
Registration timing: **prospective**

Last update: **2022-10-25, 1401/08/03**
Update count: **0**

Registration date

2022-10-25, 1401/08/03

Registrant information

Name

mohammadreza mobayen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 8540

Email address

maziar.mobayen@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of intravenous tranexamic acid on bleeding during burn surgery: a double blinded clinical trial

Public title
Tranexamic Acid in bleeding during burn surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients age between 18 and 50 severe burn (TBSA>20%) candidate for burn surgery
Exclusion criteria:
history of cardiovascular disease Liver or kidney injury pregnancy or lactating occular pathologies different coagulopathies history of allergy to Tranexamic acid
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, in order to allocate patients to intervention and control groups, a randomization method limited by the block randomization method will be used. Blocking is usually used to balance the number of samples assigned to each of the studied groups. This feature helps the researcher to equal the number of samples assigned to each of the studied groups in cases where intermediate analysis is required during the sampling process. In this study, by equal to the size of blocks, blocks with size 6 (three participants in the intervention group and three participants in the control group) will be used.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who have entry criteria and do not have non-entry criteria will be included in the study after obtaining informed consent. The file number and specifications of each patient will be recorded in predetermined forms. Then, according to the file number and using computer software, they enter one of the two groups of α and β group. This division is carried out by the statistician and the results are provided to the medical records officer of the operating room in closed envelopes. Then, based on the file number in each envelope and the clinical trial code allocated, that person will be a candidate for Tranexamic Acid or standard treatment. The surgeon (responsible for the implementation of burn surgery), the operating room assistant (responsible for recording patient information in predetermined lists), the head of the medical records unit of the operating room, the patient, the anesthesiologist, and the anesthesiologist are not informed of the contents of the envelope and the type of treatment of each patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Burn and Regerenative Medicine Research Center, Poursina four-way, Namjoo Street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Approval date
2022-08-17, 1401/05/26
Ethics committee reference number
IR.GUMS.REC.1401.294

Health conditions studied

1

Description of health condition studied
Burn Injury
ICD-10 code
خونریزی از
ICD-10 code description
T81.0

Primary outcomes

1

Description
Bleeding volume during burn surgery
Timepoint
During surgery
Method of measurement

1. Blood in the suction machine.2. For each simple surgical gas that is completely impregnated with blood, 20 cc and 40 cc of bleeding will be calculated for each longaze that is completely impregnated with blood.3. The amount of bleeding in the field of surgery: This amount will be expressed according to the estimates of the surgeon and anesthesiologist. In the ninth edition of the Burn Overall Care Book published in 2018, Herndon et al. presented an improved version of the Gross formula first used in 1983, in which the rate of in-operation bleeding is calculated in three main sections. In the first section, the expected blood volume in the patient is calculated. The second section is the fraction of lost blood, which is calculated based on hematocrit before and after surgery. The third section is the amount of volume transferred to the patient during surgery to consider the effects of fluid therapy and its progress effects during surgery on the amount of bleeding. It should be noted that since there is no physician's opinion and the results are expressed subjectively, it will have the lowest bias. Therefore, the main primary outcome in this study is the result of the above formula in CC.

Secondary outcomes

1

Description
blood transfusion
Timepoint
during and in the 24hours of surgery
Method of measurement
packed cells received

Intervention groups

1

Description
Severe burn patients with good hemodynamic status enter the operating room and undergo anesthesia. In the β group (receiving 10mg/kg tranexamic acid infusion before surgery) before induction of anesthesia, 10mg/kg of tranexamic acid solution in normal saline serum will be infused for 5 minutes. Then, the patient will be anesthetized under the supervision of an anesthesiologist. Then, from the onset of surgery to the end of the surgery, 1mg/kg of the same substance will be infused into the serum every hour. Hemodynamic status and bleeding rate are calculated. Necessary support is induced for the hemodynamic balance of patients. At the same time, drug and placebo infusion continues during surgery. At the end of the surgery, the mentioned items are set up by an anesthesiologist and burn specialist in a questionnaire and the patient is transferred to recovery. In the recovery section, a blood sample is taken to measure the amount of hemoglobin, hematocrit, and coagulation profile.
Category
Treatment - Drugs

2

Description
Control group: Severe burn patients with good hemodynamic status enter the operating room and undergo anesthesia.In the alpha group (receiving 10mg/kg saline infusion before surgery) before induction of anesthesia, 10mg/kg of normal saline serum will be infused for 5 minutes. Then, the patient will be anesthetized under the supervision of an anesthesiologist. Then, from the onset of surgery to the end of the surgery, 1mg/kg of the same substance will be infused into the serum every hour(for the sake of blinding process). Hemodynamic status and bleeding rate are calculated. Necessary support is induced for the hemodynamic balance of patients. At the same time, drug and placebo infusion continues during surgery. At the end of the surgery, the mentioned items are set up by an anesthesiologist and burn specialist in a questionnaire and the patient is transferred to recovery. In the recovery section, a blood sample is taken to measure the amount of hemoglobin, hematocrit, and coagulation profile.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Burn Center
Full name of responsible person
Mohammadreza Mobayen
Street address
Velayat Hospital, Namjoo Street, Rasht, Guilan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Deputy of Research and Technology, in front of 17 Shahrivar Hospital, Namjo St
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
mohammadreza mobayen
Position
associate professor
Latest degree
Subspecialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary

Not applicable