

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Tranexamic acid in tumescent solution on blood loss in liposuction

Protocol summary

Study aim

The effect of tranexamic acid injection on bleeding in liposuction

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 20 patients. The intervention and control group is a single patient and we will use the drug on one side and the placebo on the other side of this patient. The intervention and control sides of the patient (left or right sides) will be chosen randomly with the help of a random number table.

Settings and conduct

Patients are operated on in 15 Khordad and Shahid Modarres hospitals in Tehran. Patients are unaware of the side the drug is used. The surgeon is not informed of the side of that the drug is used. The surgeon marks the left and right specimens and hands them to the researcher and the researcher does not know which specimen is for the left or right side. The hemoglobin of the samples is measured and the bleeding volume is determined by the Klein formula and compared on both sides.

Participants/Inclusion and exclusion criteria

Entry condition: Patients who undergo liposuction in 15 Khordad or Shahid Modarres hospitals in Tehran
Conditions of non-entry: - Diabetic patients - BMI above 35 - Renal failure - coagulation problems - Patients taking aspirin or warfarin or another anticoagulant - Patients with a history of DVT or CVA or thromboembolism - Patients who have previously undergone liposuction or abdominoplasty

Intervention groups

In these patients, on one side of the body (for example, left or right side), tranexamic acid is used in the solution injected for liposuction, and the drug is not used on the opposite side, and then liposuction is performed and the amount of blood loss on both sides is compared.

Main outcome variables

The amount of volume injected The amount of suctioned

volume Preoperative hemoglobin The volume of suctioned blood on the control side The volume of suctioned blood on the case side

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210124050124N1**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Hatef Zirakzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2615 3126

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Tranexamic acid in tumescent solution on blood loss in liposuction

Public title
The effect of Tranexamic acid on blood loss in liposuction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who refer to 15 Khordad or Shahid Modarres hospitals in Tehran for liposuction.
Exclusion criteria:
 Diabetic patients Body mass index more than 35 Renal insufficiency Coagulation disorders Aspirin or Warfarin use Deep vein thrombosis or CVA or thromboemboli history Previous liposuction or abdominoplasty

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
 Target sample size: **20**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 In each patient, Tranexamic acid is used on one side in the tumescent solution for liposuction and the drug is not used on the other side.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the intervention and control group is in fact a single patient and we will use the drug on one side and the placebo on the other side of this patient. The intervention and control sides of the patient (left or right sides) will be chosen randomly with the help of a random number table.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participating patients are unaware of which side of the drug is being used and are unconscious. Also, the surgeon who performs the liposuction is not informed on which side the medicine was used in the injected solution. The surgeon marks the left and right specimens and hands them to the researcher to measure the amount of bleeding, and the researcher does not know which specimen is for the left and which is for the right.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of medicine- Shahid Beheshti university of medical sciences

Street address

Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.SBMU.MSP.REC.1398.866

Health conditions studied

1

Description of health condition studied

Blood loss in liposuction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Volume of suctioned blood on case and control sides (ml)

Timepoint

The patient's hemoglobin is measured one day before surgery. After injecting tumescent solution, we will wait for 15 minutes and then start suctioning. After suctioning, the canister containing the suctioned fluid is left in place for one hour and then a sample is sent to measure hemoglobin.

Method of measurement

The amount of injected and suctioned fluid is measured in milliliters with containers. The amount of suctioned fluid hemoglobin and the patient's blood hemoglobin are measured in grams per deciliter by a hematology analyzer.

Secondary outcomes

empty

Intervention groups

htfzrk@yahoo.com

1

Description

Intervention group: On one side of the patient's body, Tranexamic acid 500 mg per liter of normal saline is added to the tumescent solution used for suction. Wait 15 minutes then start the suction.

Category

Treatment - Surgery

2

Description

Control group: On the control side, tranexamic acid is not added to the tumescent solution of liposuction, and after 15 minutes, suctioning begins on this side.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

15 Khordad hospital - Tehran

Full name of responsible person

Hatef Zirakzadeh

Street address

Azodi street, Karimkhan Zand street, South Shahid
Azodi Street

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2

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Hatef Zirakzadeh

Street address

Yadegar Emam street, Intersection with Saadat Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Rezghi

Street address

Headquarters Building 2- Floor 5 - Shahid Beheshti
University of Medical Sciences and Health Services -
Yemen St. -- Shahid Abbas Arabi St. (Parvaneh) - Next
to Taleghani Hospital -Shahid Chamran Highway -

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hatef Zirakzadeh

Position

Resident of plastic surgery

Latest degree

Subspecialist

Other areas of specialty/work

Plastic surgery

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Patient data such as age, sex, body mass index, preoperative hemoglobin, injected and suctioned volume, and measured bleeding volume can be shared.

When the data will become available and for how long

The time for publishing this documents is three months after the publication of the article.

To whom data/document is available

The data will be available to researchers working in scientific and academic institutions.

Under which criteria data/document could be used

Documents will be available if you provide valid academic or official evidence of similar or other applied studies.

From where data/document is obtainable

To provide information, contact the responsible author of the article named Hatef Zirakzadeh by e-mail haterf.zirak@sbmu.ac.ir or htfzrk@yahoo.com.

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

The request for documentation will be discussed by the responsible author with other researchers and will be submitted to the applicant within one month if approved.

Comments