

# 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

hatef.zirak@sbmu.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

15987 64514

##### Phone

+98 21 8894 3434

##### Email

hatef.zirak@sbmu.ac.ir

### 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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1998734383

##### Phone

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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 Rezaghi

##### 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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Tehran

##### Province

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##### Phone

+98 21 2243 9780

##### Email

Mpajouhesh@sbmu.ac.ir

#### 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

##### Street address

#504, Building C, 32nd st, Feizieh st, Nivaran st

##### City

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Latest degree**  
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**City**  
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**Province**  
Tehran  
**Postal code**  
1977151988  
**Phone**  
+98 21 2615 3126  
**Fax**  
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hatef.zirak@sbmu.ac.ir

## 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 hatef.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