

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Intrauterine Instillation of Tranexamic Acid on Postoperative Hemoglobin in Hysteroscopic Myomectomy

Protocol summary

Study aim

Determining the effect of intrauterine instillation of Tranexamic Acid on postoperative hemoglobin level in hysteroscopic myomectomies

Design

A phase 3 randomized controlled double-blinded clinical trial, with parallel groups, of 70 patients. For randomization, the block randomization method and STATA software will be used.

Settings and conduct

1. Study setting: Laparoscopic ward of Arash Women's Hospital in Tehran 2. Blinding: Triple blinded 3. Blinding description: The surgeon is not aware of the presence of tranexamic acid in the media; Therefore, the surgeon, the patient, and the person evaluating the outcome (who is the surgeon herself) do not know the type of media used. The statistician is also unaware of all the processes performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: One submucosal myoma smaller than 4 cm; candidates for hysteroscopic myomectomy. Non-inclusion criteria: pelvic and uterine disorders; cancer; underlying diseases; using anticoagulant agents

Intervention groups

Intervention group: Tranexamic Acid media. Control group: Routine Media (Normal Saline).

Main outcome variables

Post-operative hemoglobin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006640N8**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2021-03-07, 1399/12/17**

Update count: **0**

Registration date

2021-03-07, 1399/12/17

Registrant information

Name

Zahra Asgari

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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asgariza@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intrauterine Instillation of Tranexamic Acid on Postoperative Hemoglobin in Hysteroscopic Myomectomy

Public title

Intrauterine Instillation of Tranexamic Acid in Hysteroscopic Myomectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with one submucosal myoma Myoma should be completely in the endometrial cavity or extending less than 50% into the myometrium (type 0 and 1, based on FIGO's classification) Myoma size less than 4 cm in the largest diameter confirmed by accurate transvaginal ultrasound Candidates for hysteroscopy and myomectomy

Exclusion criteria:

Pelvic infections History of uterine or cervical cancer; Hematological, cardiovascular, thromboembolic, hepatic, and renal disorders; or Thromboembolic events Taking anticoagulant agents Uterine septum, or uterine disorders

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we will use the block randomization method that will be designed by the epidemiologist using STATA software, version 13. The number of blocks is considered to be 6. The random allocation list will be only available to the operation room nurse. To conceal the random allocation process, 70 treatment cards written in order, will be placed in sealed envelopes. When the surgeon determines the patient's eligibility, the nurse opens the envelope related to the type of intervention and determines the type of media that should be used for the patient according to the contents of the envelope and provides it to the surgeon's assistant, who has no role in conducting the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Occasionally, normal saline is used at room temperature as a distending medium in this surgery, which will also be used in the control group. In the intervention group, 0.5 g of tranexamic acid ampoule per 1000 cc of distending medium will be dissolved and used. The surgeon is not aware of the presence of tranexamic acid in the distending medium and immediately after the surgery will record study variables without knowing the type of medium used; Therefore, the surgeon, the patient, and the outcome assessor (the surgeon) are not aware of the type of media and intervention. Also, for data analysis, a statistician who is separate from the

study process and is unaware of all the processes will perform analyses. Also, a statistical expert who is not aware of the type of interventions will analyze the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Research and Technology Dept, Sixth Floor of Central University Building, Corner of Quds Street, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.937

Health conditions studied

1

Description of health condition studied

Submucous leiomyoma of uterus

ICD-10 code

D25.0

ICD-10 code description

Submucous leiomyoma of uterus

Primary outcomes

1

Description

Hemoglobin Level

Timepoint

Once before surgery and once 24 hours after surgery

Method of measurement

Blood Test

Secondary outcomes

1

Description

Amount of bleeding

Timepoint

Immediately after surgery

Method of measurement

Checklist

2

Description

Surgeon's field of view

Timepoint

Immediately after surgery

Method of measurement

Checklist

3

Description

Duration of surgery

Timepoint

Immediately after surgery

Method of measurement

Checklist

4

Description

The amount of medium used

Timepoint

Immediately after surgery

Method of measurement

Checklist

5

Description

Complications during surgery (Uterine perforation)

Timepoint

Immediately after surgery

Method of measurement

Checklist

6

Description

Completing myomectomy

Timepoint

Immediately after surgery

Method of measurement

Checklist

7

Description

Rare side effects of Tranexamic Acid (Pulmonary embolism)

Timepoint

Immediately after surgery

Method of measurement

Checklist

8

Description

Rare side effects of Tranexamic Acid (Headache)

Timepoint

Immediately after surgery

Method of measurement

Checklist

9

Description

Rare side effects of Tranexamic Acid (abdominal cramps)

Timepoint

Immediately after surgery

Method of measurement

Checklist

10

Description

Rare side effects of Tranexamic Acid (Weakness)

Timepoint

Immediately after surgery

Method of measurement

Checklist

11

Description

Rare side effects of Tranexamic Acid (Back Pain)

Timepoint

Immediately after surgery

Method of measurement

Checklist

12

Description

Rare side effects of Tranexamic Acid (Cramps and Muscle Spasms)

Timepoint

Immediately after surgery

Method of measurement

Checklist

13

Description

Complications during surgery (Thermal injury)

Timepoint

Immediately after surgery

Method of measurement

Checklist

14

Description

Complications during surgery (Overload of distention media)

Timepoint

Immediately after surgery

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: In the intervention group, tranexamic acid ampoule with a dose of 0.5 g per 1000 cc of normal saline distending medium will be used (considering that the injection dose is 1 gram and can be repeated every 6 to 8 hours and can be used in electrolyte solutions according to the manufacturer's instructions).
(Manufactured by Caspian Tamin Pharmaceutical)

Category

Treatment - Drugs

2

Description

Control group: In the control group, according to the routine, only normal saline will be used as distending medium.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Dr. Zahra Asgari

Street address

Arash Women Hospital, Corner of 162 Alley (Shahid Abdolmajid), Next to Police Station 126, Shahid Baghdarnia Street (North Rashid), After Shahid Bagheri Highway, Resalat Highway.

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Sponsors / Funding sources

1

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Venus Chegini

Position

Fellowship in Minimally Invasive Gynecologic Surgery

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Associate Professor

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

Not applicable

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Venus Chegini

Position

Fellowship in Minimally Invasive Gynecologic Surgery

Latest degree