Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of intrauterine tranexamic acid on bleeding and the outcome of it in hysteroscopic myomectomy

Protocol summary

Study aim

The effect of intrauterine tranexamic acid in hysteroscopic myomectomy

Design

In this phase3 clinical trial, with case group and control group, 60 patients are randomly divided into two groups of 30 using block randomization. This study is done in a double blind.

Settings and conduct

Candidates for myomectomy hysteroscopy, who will refer to Afzalipur Hospital in Kerman, will be divided into two placebo or intervention groups, and the intervention group will be given drug (TXA) and the other group will be given placebo (normal saline). The information related to the variables during surgery will be recorded by the operating room nurse and the information related to the variables after surgery by the relevant resident in the data collection form. The data will be recorded by an independent person (statistician) who is not involved in the treatment or data collection. The principal investigator, the patients, and the surgeon performing the surgery will all be blinded to the trial.

Participants/Inclusion and exclusion criteria

Entry: age 18 to 60 years; Solitary myoma; Type 0, 1, and 2 myomas; Myomas smaller than 4 cm non-entry:lack of consent; active pelvic infection; previous history of hysteroscopy; pregnancy; multiple myomas; Uterine abnormalities; myomas larger than 4 cm or grade more than 2; thrombotic diseases; Use of thrombolytic drugs up to 2 weeks after surgery

Intervention groups

The intervention group will be injected with a drug (TXA 10 mg/kg from Iran Daru Company) and the other group will be injected with placebo (5cc N.S) before the start of hysteroscopy, and the amount of bleeding, success and complications will be checked.

Main outcome variables

Age; BMI; type of myomas; the number of myoms; better vision during operation; Bleeding during surgery; operation duration; decrease in hemoglobin; Complications of the operation; The completeness of the operation in one step

General information

Reason for update

Acronym

Tranexamic acid (TXA) - Normal salin (N.S)

IRCT registration information

IRCT registration number: **IRCT20230316057738N1**
Registration date: **2023-05-19, 1402/02/29**
Registration timing: **prospective**

Last update: **2023-05-19, 1402/02/29**
Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

Nadia Arabpour amroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3216 8180

Email address

arabpour.nadia@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of intrauterine tranexamic acid on bleeding and the outcome of it in hysteroscopic myomectomy

Public title
Investigating the effect of tranexamic acid drug on bleeding and surgical outcomes of myoma removal through hysteroscope
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Have a single myoma Grade 0, 1, and 2 myomas Myomas smaller than 4 cm
Exclusion criteria:
Have intracranial bleeding Have any sensitivity to the drug tranexamic acid Have thromboembolic and ischemic heart diseases There are uterine abnormalities Have an active pelvic infection Have a history of hemorrhagic disease Pregnancy Previous hystreroscopy surgery
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the Restricted randomization method of block block randomization 1:1, and the patients will be divided into two groups: placebo (30 people) or intervention (30 people) and the drug intervention group (tranexamic acid) 10 mg/kg) and placebo (normal saline) will be given to the other group. (Blocking is usually used in order to balance the number of samples allocated to each of the studied groups. This feature helps researchers to increase the number of samples in cases where intermediate analyzes are needed during the sampling process. allocated to each of the studied groups is the same) the size of all the blocks is equal and in this experiment we will have two groups of 6 blocks (including 3 participants in the intervention group and 3 participants in the control group) had The randomization tool is also used from software allocation random sequence generation software, which in addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method.
Blinding (investigator's opinion)
Double blinded
Blinding description
An independent person (statistician) who is involved in the treatment or collection of data will be sealed with consecutive numbers. The principal investigator, the patients, and the surgeon performing the surgery will all be blinded to the trial. All participants will undergo a thorough clinical evaluation including: detailed history, general and pelvic examination, transvaginal ultrasound to determine the number, size and location of myomas. After preparing the history and clinical examinations, blood samples of the patients will be prepared and the necessary tests (CBC), PT, PTT and INR will be done for them before the surgery. Also, drug or placebo is prescribed using a specific coding system, and the surgical team and the patient themselves do not know the type of drug used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
University of Medical Sciences Campus,The beginning of Haft Bagh Alavi Boulevard, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2023-05-01, 1402/02/11
Ethics committee reference number
IR.KMU.AH.REC.1402.017

Health conditions studied

1

Description of health condition studied
Uterus myoma
ICD-10 code
D25.9
ICD-10 code description

Leiomyoma of uterus, unspecified

Primary outcomes

1

Description
Better vision during surgery
Timepoint
During surgery
Method of measurement
Surgeon rating

2

Description
Bleeding during surgery
Timepoint
During surgery
Method of measurement
Surgeon rating

3

Description
Duration of operation
Timepoint
From the beginning of surgery to the end of surgery
Method of measurement
Minutes

4

Description
Hemoglobin reduction rate
Timepoint
Before the operation and 24 hours after the operation
Method of measurement
Milligram on deciliter

5

Description
Complications of the operation
Timepoint
During or after surgery
Method of measurement
Patient symptoms

6

Description
The completeness of the operation in one step
Timepoint
One month after surgery
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: as soon as the hysteroscope enters the uterus, an ampoule of tranexamic acid from Iran Daru 10 mg/kg will be injected into the uterus.p:
Category
Treatment - Drugs

2

Description
Control group: As soon as the hysteroscope enters the uterus, 5 cc of normal saline will be injected into the uterus
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Nadia Arabpour amroudi
Street address
Kerman medical university Campus, The beginning of Haft Bagh Alavi Ave., Kerman, Iran
City
Kerman
Province
Kerman
Postal code
Phone
+98 34 3132 8000
Fax
Email
arabpour.nadia@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Nadia Arabpour amroudi
Street address
Kerman University of Medical Sciences Campus, The beginning of Haft Bagh Alavi Ave.
City
Kerman
Province
Kerman
Postal code
7616913555
Phone

+98 34 3226 3855

Email

arabpour.nadia@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nadia Arabpour amroudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vasal Alley 1 , Vasal St.

City

Kerman

Province

Kerman

Postal code

7617945661

Phone

+98 34 3216 8180

Email

arabpour.nadia@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nadia Arabpour Amroudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vasal Alley 1, Vasal St.,

City

Kerman

Province

Kerman

Postal code

7617945661

Phone

+98 34 3216 8180

Email

arabpour.nadia@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nadia Arabpour amroudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vesal Alley 1, Vasal St.

City

Kerman

Province

Kerman

Postal code

7617945661

Phone

+98 34 3216 8180

Email

arabpour.nadia@gmail.com

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

All of datas

When the data will become available and for how long

Starting from six months after the publication of the article

To whom data/document is available

Researchers, students and doctors

Under which criteria data/document could be used

To conduct a clinical trial

From where data/document is obtainable

Public or scientific responsible person

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

Send the proposal to the responsible person's email

Comments