

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparative study of intravenous tranexamic acid and intravenous oxytocin in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterin bleeding

#### Protocol summary

##### Summary

The main objective of this study is comparative study of intravenous tranexamic acid and intravenous oxytocin in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterin bleeding. The study included 140 patients with complaints abnormal uterine bleeding that refer to Alzahra hospital for hysteroscopic myomectomy will be done. Patients randomly using random software list will be divided into two groups of 70 people. Patients with abnormal uterine bleeding and submucosal myoma with a diameter of 30 mm or less and zero or first grade will be incloud to this study. of All patients in both groups of informed consent will be obtained. Both groups were matched for age, gravid, parity and the number of myoma And patients with a history of underlying disease, submucosal larger than 3 cm will be excluded. Random selection will be done by a nurse, that aware of the details of an investigation. Doctors and patients to selected groups will be blind. In both groups after general anesthesia and cervical dilatation, 5% dextrose solution will be used as the medium for uterine cavity distention and will be withdraw completely myoma and Upon entering hysteroscop in to uterus, the first group received tranexamic acid 10 mg / kg in 500 ml Ringer serom in 10 minutes and the second group, five units of oxytocin in 500 ml serum ringer 10 minute intravenous infusion at will In this study, the changes of hemoglobin as the primary outcome and duration of surgery and the success rate in Myomectomy, is considered secondary outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105306563N2**

Registration date: **2016-10-25, 1395/08/04**  
Registration timing: **registered\_while\_recruiting**

Last update:  
Update count: **0**

**Registration date**  
2016-10-25, 1395/08/04

##### Registrant information

**Name**  
Mehri Jafari Shobeiri  
**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Country**  
Iran (Islamic Republic of)  
**Phone**  
+98 41 1553 9161  
**Email address**  
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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

##### Expected recruitment start date

2016-10-17, 1395/07/26

##### Expected recruitment end date

2018-02-15, 1396/11/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of intravenous tranexamic acid and

intravenous oxytocin in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterin bleeding

## Public title

Comparative study of intravenous tranexamic acid and intravenous oxytocin in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterin bleeding

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Medium and persistent abnormal uterine bleeding; Report on transvaginal ultrasound submucosal myoma diameter 30 mm or less and grade zero or one; Exclusion criteria: Patients with a history of heart disease; Hepatic; Diabetes; Thromboembolism; Cancer of the uterus and cervix; Submucosal leiomyoma larger than 3 cm; Uterine septum; pregnant women; Severe bleeding; Anti coagulation therapy

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences.

##### Street address

Third Floor, Central Building of Number2, Golgasht Street

##### City

Tabriz

##### Postal code

#### Approval date

2016-10-05, 1395/07/14

## Ethics committee reference number

IR.TBZMED.REC.1395.689

## Health conditions studied

### 1

#### Description of health condition studied

Abnormal uterine and vaginal bleeding

#### ICD-10 code

N93

#### ICD-10 code description

Other abnormal uterine and vaginal bleeding

## Primary outcomes

### 1

#### Description

The hemoglobin concentration

#### Timepoint

Six hours after surgery

#### Method of measurement

Blood test

## Secondary outcomes

### 1

#### Description

Duration of surgery.

#### Timepoint

After surgery

#### Method of measurement

Questionnaire

### 2

#### Description

The success of myomectomy

#### Timepoint

After surgery

#### Method of measurement

Observation

## Intervention groups

### 1

#### Description

the first group received tranexamic acid 10 mg / kg in 500 ml Ringer serom in 10 minutes

#### Category

Treatment - Drugs

### 2

#### Description

The second group, five units of oxytocin in 500 ml serum ringer 10 minute intravenous infusion

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Dr.Mehri Jaefari Shobeiri

**Street address**

Alzahra Hospital, South Artesh St.,Tabriz, iran

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for Research,Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr.Alireza Rashidi

**Street address**

Third Floor, Central Building of Number2, Golgasht Street

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for Research,Tabriz University Of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Mehri Jaefari Shobeiri

**Position**

Professor of Obstetrics and Gynecology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*