

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

jafarim@tbzmed.ac.ir

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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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