

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison the intraoperative outcomes of intrauterine instillation of E-Aminocaproic Acid and intravenous oxytocin in hysteroscopy surgeries

Protocol summary

Summary

The main objective of this study is Comparing the intraoperative outcomes of intrauterine instillation of E-Aminocaproic Acid and intravenous oxytocin in hysteroscopy surgeries. This study is a single blind clinical trial. The study included 144 patients with Treatment resistant abnormal uterine bleeding that hospital visit and has been nominated for hysteroscopy can be performed and are divided in to two groups(77 person). Patients with endometrial thickening, and submucosal uterine myoma less than 5 cm include and the patient with hepatic renal and cardiovascular disorders, and metabolic diseases will be excluded. In the first group two grams of E-Aminocaproic Acid per liter of 5% dextrose saline for intrauterine induction and hysteroscopy used and in the second group only5% dextrose saline for uterine and intravenous 10 IU / L oxytocin used during surgery. for both groups Suitable Temperature of serum is room temperature. Hysteroscopy minute period for both groups will be identified. The primary outcome was to determine the amount of bleeding during surgery with using a visual scale would be zero(no hemorrhage) to 4 (severe bleeding passing clots) will be different. Anesthetic peri operative complications were reported as secondary outcomes. Prepare serum and the drug will be done by the operating room nurse and surgeon in all cases, a person will be. All under general anesthesia and placed in amanner and form. Blood transfusion and post operative hospital stay were reported.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409235283N10**

Registration date: **2014-10-14, 1393/07/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-14, 1393/07/22

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Expected recruitment start date

2014-10-24, 1393/08/02

Expected recruitment end date

2015-10-24, 1394/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the intraoperative outcomes of intrauterine instillation of E-Aminocaproic Acid and intravenous oxytocin in hysteroscopy surgeries

Public title

Comparison the intraoperative outcomes of intrauterine instillation of E-Aminocaproic Acid and intravenous

oxytocin in hysteroscopy surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: history of persistent uterine bleeding accompanied with endometrial thickness, endometrial polyp or submucous myoma less than 5 cm in diameters and patients' willing to participate Exclusion criteria: Patients with the history of cardiopulmonary and liver disease, hypertension, diabetes, hyperlipidemia, cervical and uterine cancers, submucous myomas more than 5 cm in diameters

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht Street ,Tabriz University Of Medical Sciences

City

Tabriz

Postal code

Approval date

2014-06-26, 1393/04/05

Ethics committee reference number

9344

Health conditions studied

1

Description of health condition studied

Polyp of corpus uteri

ICD-10 code

N84.0

ICD-10 code description

Polyp of corpus uteri

2

Description of health condition studied

endometrial tickness

ICD-10 code

N85.0

ICD-10 code description

Endometrial glandular hyperplasia

3

Description of health condition studied

Submucous leiomyoma

ICD-10 code

D25.0

ICD-10 code description

Submucous leiomyoma of uterus

Primary outcomes

1

Description

Interaoperative bleeding

Timepoint

at the end of surgery

Method of measurement

Visual scale

2

Description

duration of surgery

Timepoint

from the beginning to the end of surgery

Method of measurement

Questionnaire

3

Description

volume of injected media

Timepoint

after finishing of every one litre serum

Method of measurement

number of injected serums

Secondary outcomes

1

Description

blood pressure

Timepoint

continious

Method of measurement

monitor

2

Description

bradycardia

Timepoint

continious

Method of measurement

monitor

3

Description

gastrointestinal side effects

Timepoint

every 1 hour

Method of measurement

clinical signs and symptoms

4

Description

headache

Timepoint

every 1 hours

Method of measurement

clinical symptoms

5

Description

post operative bleeding

Timepoint

every 15 minuts

Method of measurement

clinical signs and symptoms

6

Description

duration of hospital stay

Timepoint

From admission to discharge

Method of measurement

Questionnaire

Intervention groups

1

Description

Group B: placebo i.e., dextrose 5% in the same form inside one liter of the dextrose 5%

Category

Placebo

2

Description

Group A: E-Aminocaproic Acid in dextrose 5% inside one liter of the dextrose 5%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Dr.Manizheh Sayyah-Melli

Street address

Alzahra Hospital, South Artesh Ave

City

T

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

Dr.Manizhe Sayyah-Melli

Position

prof. of Ob & Gyn

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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