

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Effect of administration of oxytocin and calcium chloride combination on blood loss during abdominal myomectomy

#### Protocol summary

##### Study aim

Determine the effect of infusion of oxytocin and calcium in the amount of bleeding during abdominal myomectomy

##### Design

Clinical trial on two groups including intervention and control groups with parallel groups which are randomly assigned and single-blinded. each group 25 patient

##### Settings and conduct

The aim of this study was to identify patients with uterine lymphoma for abdominal myomectomy at Tabriz Alzahra Medical Education Hospital in the operating room. Considering the average hemorrhage rate of  $150 \pm 300$  ml in abdominal myometectomy with oxytocin alone (control group) and a prediction of a 50% reduction in the amount of intraoperative bleeding in the simultaneous use of calcium chloride and oxytocin (study group) Using PS power & sample size calculation software (Version 3.0, 2009) with a probability of dropping 10% in patients, In each group, 25 people will randomly enter the study.

##### Participants/Inclusion and exclusion criteria

Write: Healthy female abdominal myomectomy candidate • Age over 30 years • Pre-operative ionized calcium values within normal range Non arrival: • Patients with a laparoscopic or hysteroscopic myomectomy candidate • Patients consuming GnRH agonist before surgery • Patients with a history of heart, lung, kidney, liver, metabolic and ...

##### Intervention groups

Patients in the study group (25 cases), 30 units of oxytocin and 1 g of calcium chloride in 120 ml of normal saline serum in 120 minutes (at a rate of 1 ml / min) intravenously through a separate iv catheter, after incision of the skin to The last uterine suture is obtained after separating the myoma. In the patients in the placebo group (25 cases), the same volume of saline solution is given without a medication.

##### Main outcome variables

Systolic blood pressure changes; diastolic blood pressure changes; mean arterial blood pressure changes; Heart rate changes; Heart rhythm chang

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110712007013N23**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

##### Registration date

2019-07-06, 1398/04/15

##### Registrant information

##### Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of administration of oxytocin and calcium chloride combination on blood loss during abdominal myomectomy

**Public title**

Effect of administration of oxytocin and calcium chloride combination on blood loss

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Healthy female abdominal myomectomy Age over 30 years Pre-operative ionized calcium values within normal range

**Exclusion criteria:**

Patients with a laparoscopic or hysteroscopic myomectomy candidate • Patients consuming GnRH agonist before surgery Patients with a history of heart, lung, kidney, liver, metabolic and ... History of oxytocin or calcium allergy Patients treated with digitalis drugs,  $\beta$ -adrenergic blocker and calcium blocker Patients with coagulation disorders Thrombocytopenia (platelet  $100000 / \text{mm}^3 >$ )

**Age**

From 30 years old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Care provider
- Outcome assessor

**Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the patients to intervention and control groups will be performed using the random numbered table technique via Randlist online software, individually for patients. A random numbered table is a collection of numbers that are generated without a specific pattern or order and in a completely random manner. In this study, the odd numbers were assigned to the control group and the even numbers to the intervention group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Anesthesiologist has the responsibility of anesthesiology, patient monitoring and preparation of study solutions, and the thesis student who is unaware of the study group. is responsible for collecting information and variables of patient.

**Placebo**

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**

Vice chancellor for research, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5183915881

**Approval date**

2018-04-23, 1397/02/03

**Ethics committee reference number**

IR.TBZMED.REC.1397.103

**Health conditions studied****1****Description of health condition studied**

Blood loss during Abdominal Myomectomy

**ICD-10 code**

Diseases o

**ICD-10 code description**

N80-N98

**Primary outcomes****1****Description**

Low blood pressure

**Timepoint**

immediate after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

**Method of measurement**

Patient monitoring / Barometric device

**2****Description**

Tachycardia

**Timepoint**

immediate after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

## Method of measurement

Patient monitoring

### 3

#### Description

Sweating

#### Timepoint

immediate after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

#### Method of measurement

Ask the patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in the study group (25 cases), 30 units of oxytocin and 1 g of calcium chloride in 120 ml of normal saline serum in 120 minutes (at a rate of 1 ml / min) intravenously through a separate iv catheter, after incision of the skin to The last uterine suture is obtained after separating the myoma.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In the patients in the placebo group (25 cases), the same volume of saline solution is given without a medication. After the completion of surgery, the patients are transferred to the post-anesthetic care unit (PACU) and transferred to the surgery department after obtaining Alder score of 10-9.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Simin Atashkhoyi

##### Street address

Alzahra hospital, South artesh street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138663134

##### Phone

+98 41 3553 9163

##### Email

alzahrahosp@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Abolghasem Jouyban

##### Street address

Research and innovation deputy, third floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665931

##### Phone

+98 41 3335 7310

##### Email

research-vice@tbzmed.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Simin Atashkhoyi

##### Position

Professor, Specialist in anesthesiology

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Al Zahra hospital, Baghshomal square

##### City

Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5138663134  
**Phone**  
+98 41 1553 9161  
**Email**  
atashkhoyi@tbzmed.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Simin Atashkhoyi  
**Position**  
Professor, Specialist in anesthesiology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Al Zahra hospital, Baghshomal square  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5138663134  
**Phone**  
+98 41 1553 9161  
**Email**  
atashkhoyi@tbzmed.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Simin Atashkhoyi  
**Position**  
Professor, Specialist in anesthesiology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Al Zahra hospital, Baghshomal square  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5138663134  
**Phone**  
+98 41 1553 9161  
**Email**  
atashkhoyi@tbzmed.ac.ir

## 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

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