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 ± 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 Siences

Country
Iran (Islamic Republic of)

Phone
+98 41 3333 3806

Email address
atashkhoii@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, β-adrenergic blocker and calcium blocker Patients with coagulation disorders Thrombocytopenia (platelet 100000 / mm3>)
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
atashkhoii@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
atashkhoii@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
atashkhoii@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