Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oxytocin infusion on reducing operative blood loss during abdominal myomectomy

Protocol summary

Summary

Uterine myomas are benign tumors of the uterus. Abdominal myomectomy, the surgical removal of myomas, is an important treatment option especially for women who wish to preserve their uteri.The major problem with myomectomy is excessive bleeding, which can be life threatening and prolong postoperative stay. The aim of this study, is to assess the effectiveness, and safety of oxytocin to reduce blood loss during myomectomy. In this double blind, randomized, and placebo-controlled clinical trial, 80 patients requiring surgical myomectomy by laparotomy will be study. Patients will be randomize to two groups. In the study group (40 patients) oxytocin 30 u in 1000 ml normal saline administer during myomectomy and in the placebo group (40 patients) normal saline alone will be administered. The main outcome measures are peri-operative blood loss and rates of blood transfusion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211217013N3**
Registration date: **2012-12-09, 1391/09/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-09, 1391/09/19

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

Women's Reproductive Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-08-06, 1392/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oxytocin infusion on reducing operative blood loss during abdominal myomectomy

Public title

Effect of oxytocin infusion on reducing operative blood loss during abdominal myomectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Including criteria: Women undergoing abdominal myomectomy; over 35 years age Excluding criteria: Patients candidate for hysteroscopic myomectomy; Patients with preoperative GnRH agonist consumption; Patients with history of cardiopulmonary disease

Age

From **35 years** old to **60 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences
Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah square, Tabriz
City
Tabriz
Postal code
Approval date
2012-11-04, 1391/08/14
Ethics committee reference number
91126

Health conditions studied

1

Description of health condition studied
Bleeding during abdominal myomectomy
ICD-10 code
D25
ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
The amount of bleeding
Timepoint
During myomectomy
Method of measurement
Count sponges and the amount of blood collected in the suction device - according to ml

Secondary outcomes

1

Description
The amount of blood transfusion
Timepoint
Intra and postoperative
Method of measurement
Observation, Physical examination- Blood unit according to ml

2

Description
Hb and HcT values
Timepoint
Prior to operation and 24 h after operation
Method of measurement
Elyza method-CBC[Hb(g/dl), HcT(%)}

Intervention groups

1

Description
In the study group (n=40) oxytocin 30 u into 1000 ml normal saline will be infused during myomectomy.
Category
Treatment - Drugs

2

Description
In the placebo group (n=40) normal saline alone 1000 ml will be infused during myomectomy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Operating Room and Cesarean setting, Al Zahra Hospital, Tabriz University of Medical Sciences,
Full name of responsible person
Dr. Simin Atashkhoei
Street address
Al Zahra hospital, Artesh Jonoubi Ave,Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Elahe Olade Saheb Madarek
Street address
Al Zahra hospital, Artesh Jonoubi Ave, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Health Research Center, 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
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Simin Atashkhoei
Position
Associate Professor, Specialist in Anesthesiology
Other areas of specialty/work
Street address
Al Zahra hospital, Artesh Jonoubi Ave, Tabriz
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
siminatashkhoii@yahoo.comsatashkhoyi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Women's Reproductive Health Research Center,Tabriz University of Medical Sciences
Full name of responsible person
Dr Simin Atashkhoyi
Position
Associate Professor, Specialist in anesthesiology
Other areas of specialty/work
Street address
Al Zahra Hospital, Artesh Jonoubi Ave,Tabriz
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
siminatashkhpii@yahoo.comsatashkhoyi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Simin Atashkhoyi
Position
Associate Professor, Specialist in Anesthesiology
Other areas of specialty/work
Street address
Alzahra Hospital, Artesh Jonoubi Ave, Tabriz
City
Tabriz
Postal code
Phone
+98 41 1553 9161
Fax
Email
siminatashkhoii@yahoo.comsatashkhoyi@gmail.com
Web page address

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