Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

comparative study of natural micronized progestrone and gonadotropin-releasing hormone agonist in the control of bleeding during hysterescopic myomectomy in women with abnormal uterine bleeding

Protocol summary

Study aim

The main objective of this study is comparative study of natural micronized progestrone and gonadotropin-releasing hormone agonist in the control of bleeding during hysterescopic myomectomy in women with abnormal uterine bleeding . The study included 50 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 25 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. After random selection of patients by the respective resident, the first group of 100 mg of natural micronized progesterone capsules called Utrogestan will be used , from the first day of the period for 30 days, two capsules totaling 200 mg when sleeping 3 hours from the last meal with a glass of water will be used. In the second group 2 months before hysteroscopy, the injection of muscle will be 3.75 mg of dipyriline ampoule as a GnRH agonist compound on day 21 of the period to two doses of 28 days. The first group will be admitted to the surgery on the last day of Utrogestan and the second group will be 4 weeks after the second injection of GnRH. 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.

Design

The study included 50 patients with complaints abnormal uterine bleeding that refer to Alzahra hospital for hysteroscopic myomectomy will be done.Then, patients were randomly divided into two control 1 and control 2.

Settings and conduct

The main objective of this study is comparative study of natural micronized progestrone and gonadotropin-releasing hormone agonist in the control of bleeding during hysterescopic myomectomy in women with abnormal uterine bleeding . The study included 50 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 25 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. After random selection of patients by the respective resident, the first group of 100 mg of natural micronized progesterone capsules called Utrogestan will be used , from the first day of the period for 30 days, two capsules totaling 200 mg when sleeping 3 hours from the last meal with a glass of water will be used. In the second group 2 months before hysteroscopy, the injection of muscle will be 3.75 mg of dipyriline ampoule as a GnRH agonist compound on day 21 of the period to two doses of 28 days. The first group will be admitted to the surgery on the last day of Utrogestan and the second group will be 4 weeks after the second injection of GnRH. 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.

Participants/Inclusion and exclusion criteria

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

Intervention groups

En Intervention group 1 : A 100 mg capsule of natural micronized progesterone called Utrogestan will be used, starting from the first day of the period for 30 days, two capsules of 200 mg will be used at bedtime with 3 hours from the last meal with a glass of water. En Intervention group 2: Intramuscular injection of 3.75 mg of diafililic ampoule as a GnRH agonist compound will be used on day 21 of the period two dose intervals of 28 days for 2 months prior to the hysteroscopy. .

Main outcome variables

En The hemoglobin concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110523006563N3**
Registration date: **2018-01-04, 1396/10/14**
Registration timing: **prospective**

Last update: **2018-01-04, 1396/10/14**
Update count: **0**

Registration date

2018-01-04, 1396/10/14

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

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative study of natural micronized progestrone and gonadotropin-releasing hormone agonist in the control of bleeding during hysterescopic myomectomy in women with abnormal uterine bleeding

Public title

comparative study of natural micronized progestrone and gonadotropin-releasing hormone agonist in the control of bleeding during hysterescopic myomectomy in women with abnormal uterine bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with abnormal uterine bleeding Patients with submucosal myoma with a diameter of 30 mm or less and zero or first grade

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

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will randomly be divided into two groups using the Randlist version 1, 2, Dattng CmbH, Tubingen Germany software.

Blinding (investigator's opinion)

Double blinded

Blinding description

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.

Placebo

Not used

Assignment

Crossover

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
Province
East Azarbaijan
Postal code
5138665793
Approval date
2017-11-14, 1396/08/23
Ethics committee reference number
IR.TBZMED.REC.1396.703

Health conditions studied

1

Description of health condition studied
Abnormal uterine and vaginal bleeding
ICD-10 code
ICD-10
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

Intervention groups

1

Description
Intervention group 1 : A 100 mg capsule of natural micronized progesterone called Utrogestan will be used, starting from the first day of the period for 30 days, two capsules of 200 mg will be used at bedtime with 3 hours from the last meal with a glass of water.
Category
Treatment - Drugs

2

Description
Intervention group 2: Intramuscular injection of 3.75 mg of diafililic ampoule as a GnRH agonist compound will be used on day 21 of the period two dose intervals of 28 days for 2 months prior to the hysteroscopy.
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
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com

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
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com
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
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
Mehri Jaefari Shobeiri

Position
Professor of Obstetrics and Gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 41 3553 9161

Email
lahhroudin@gmail.com

Person responsible for scientific 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

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 41 3553 9161

Email
lahroudin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehri Jaefari Shobeiri

Position
Professor of Obstetrics and Gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Tabriz University Of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5138665793

Phone
+98 41 3553 9161

Email
lahroudin@gmail.com

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