

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### **comparative study of natural micronized progesterone and gonadotropin-releasing hormone agonist in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterine bleeding**

#### **Protocol summary**

##### **Study aim**

The main objective of this study is comparative study of natural micronized progesterone and gonadotropin-releasing hormone agonist in the control of bleeding during hysteroscopic 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 includ 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 dipyrilone 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 progesterone and gonadotropin-releasing hormone agonist in the control of bleeding during hysteroscopic 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 includ 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 dipyrilone 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 included in 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 diafillic 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 progesterone and gonadotropin-releasing hormone agonist in the control of bleeding during hysteroscopic myomectomy in women with abnormal uterine bleeding

### Public title

comparative study of natural micronized progesterone and gonadotropin-releasing hormone agonist in the control of bleeding during hysteroscopic 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 diafilic 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

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Tabriz

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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

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Tabriz University Of Medical Sciences, Golgasht Street

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## 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

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## Person responsible for updating data

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## 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