

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparative study of dienogest and danazol in endometrial preparation for hysteroscopic myomectomy in patients with intrauterine myoms

Protocol summary

Study aim

Comparative study of dienogest and danazol in endometrial preparation for hysteroscopic myomectomy in patients with intrauterine myomas

Design

Phase 3 randomized clinical trial, double blinded with parallel groups, on 60 patients. Randlist with code 351656064 will be used to randomize patients.

Settings and conduct

The present study will be performed in the Women's Reproductive Health Research Center of Alzahra Teaching, Treatment and Research Hospital in Tabriz. Surgeon and operating room nurse were blinded.

Participants/Inclusion and exclusion criteria

Patients in reproductive age with moderate to severe abnormal uterine bleeding without receiving hormonal medication from 8 weeks before, who underwent transvaginal ultrasonography of the submucosal myoma with a diameter of 30 mm or less and grade zero or I according to the endoscopic European gynecology association classification were included. Patients with a history of cardiovascular, hepatic, renal, pulmonary and hematologic disease, hypertension, diabetes, high triglycerides, thromboembolism, uterine and cervical cancer, submucosal leiomyoma larger than 3 cm, acute genital infection, uterine septum, pregnancy, infertility, requiring transfusion, severe bleeding and using anticoagulants will be excluded.

Intervention groups

Intervention group 1: Dienogest 2 mg tablets will be used for up to 4 weeks from the first day of menstruation. Dienogest is prepared under the brand name of Dinovel in the form of 2 mg tablets made by Chemo, Spain by order of Iran Hormone Pharmaceutical Company. Intervention group 2: Danazole 200 mg tablets will be used from the first day of the period, one morning pill and one evening pill for up to 4 weeks. Danazole is available in the form of 200 mg tablets made by Cipla, India by order of Kimia Ara Pharmaceutical Company.

Main outcome variables

Rate of endometrial atrophy, rate of bleeding during surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110523006563N4**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-26, 1399/09/06**

Update count: **0**

Registration date

2020-11-26, 1399/09/06

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

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of dienogest and danazol in endometrial preparation for hysteroscopic myomectomy in patients with intrauterine myoms

Public title

Comparative study of dienogest and danazol in endometrial preparation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Reproductive ages Moderate to moderate abnormal uterine bleeding Do not receive hormonal medication for 8 weeks Submucosal myoma 30 mm or less in diameter in transvaginal ultrasound Submucosal myoma grade zero or I according to the classification of the European Society of Endoscopy and Gynecology

Exclusion criteria:

Cardiovascular disease Hepatic disease Renal disease Pulmonary disease Hematologic disease Hypertension Diabetes High triglyceride Thromboembolism History of uterine and cervical cancer History of submucosal leiomyoma larger than 3 cm History of acute genital infection History of the uterine septum Pregnancy Infertility Requires transfusion Severe bleeding Using anticoagulants

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups using Randlist version 1.2 Dattng GmbH, Tubingen Germany with the code 351656064.

Blinding (investigator's opinion)

Double blinded

Blinding description

Surgeon and operating room nurse are blinded. Patients do not have any medical intervention during surgery and entering the operating room. Patients' medication information will not be provided to the surgeon and the surgeon and operating room nurse will be unaware of the medication received.

Placebo

Not 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

Third Floor, Number 2 central building, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.TBZMED.REC.1399.722

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

Intrauterine myoma

ICD-10 code

D25.9

ICD-10 code description

Leiomyoma of uterus, unspecified

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

Endometrial atrophy

Timepoint

4 weeks after the intervention

Method of measurement

Vaginal ultrasound

2**Description**

Bleeding during surgery

Timepoint

After surgery

Method of measurement

Operating room suction

Secondary outcomes

1

Description

Clear image resolution

Timepoint

During surgery

Method of measurement

Observed by a gynecological surgeon

2

Description

Operation duration

Timepoint

During surgery

Method of measurement

Observed by a gynecological surgeon

3

Description

Success rate of myomectomy

Timepoint

During surgery

Method of measurement

Observed by a gynecological surgeon

Intervention groups

1

Description

Intervention group: Dienogest 2 mg tablets will be used for up to 4 weeks from the first day of menstruation. Dienogest is prepared under the brand name of Dinovel in the form of 2 mg tablets made by Chemo, Spain by order of Iran Hormone Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group: Danazole 200 mg tablets will be used from the first day of the period, one morning pill and one evening pill for up to 4 weeks. Danazole is available in the form of 200 mg tablets made by Cipla, India by order of Kimia Ara Pharmaceutical Company.

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiee

Street address

Third Floor, Number 2 central building, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3335 7310

Email

samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

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

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 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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document

The request will be sent by email to person responsible for scientific or public inquiries.

Comments