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 prepration 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 gynecologyassociation 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)

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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
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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
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Tabriz
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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

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Person responsible for scientific inquiries

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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)
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