Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of Dienogest compared to placebo in reducing dysmenorrhea in women with primary and secondary dysmenorrhea

Protocol summary

Study aim

Evaluation of the effectiveness of Dienogest compared to placebo in reducing dysmenorrhea in women with primary and secondary dysmenorrhea

Design

This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 60 women with dysmenorrhea.

Settings and conduct

In this interventional study, 60 women suffering from primary or secondary dysmenorrhea are selected by convenience sampling method in Yas Hospital. Then, 30 women will be placed in the intervention group (Dienogest prescription) and 30 women will be placed in the control group (placebo prescription) using the random allocation method. This study is double-blind, the participants (with placebo using) and the physician who evaluates the outcome are kept blind. The physician evaluating the outcome does not know the treatment group of the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria include women aged 20 to 45 years, noticeable pain in the lower abdomen or pelvic area during menstruation, regular mensuration cycles, and normal genital system physical examination and ultrasound. Exclusion criteria: patients with abnormal serum lipid profile, and chronic diseases or chronic pelvic pain.

Intervention groups

For the Intervention group, half a milligram of dienogest (a quarter of a pill) is prescribed twice a day (every 12 hours) from the second day of menstruation and is continued for 12 weeks. For the control group, the placebo (a quarter of a pill) is prescribed twice a day (every 12 hours) from the second day of menstruation and is continued for 12 weeks.

Main outcome variables

Dysmenorrhea, premenstrual symptoms, and Dienogest side effects are measured four times every four weeks during the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150105020558N5**
Registration date: **2022-09-18, 1401/06/27**
Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**
Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

Mahbod Ebrahimi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8882 7794

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maebrahimi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Dienogest compared to placebo in reducing dysmenorrhea in women with primary and secondary dysmenorrhea

Public title

The effectiveness of Dienogest in reducing dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20 to 45 years old Noticeable pain (Visual Analogue Scale>=4) in the lower abdomen or pelvic area during menstruation in the last six months With regular mensuration cycles With normal genital system physical examination and ultrasound

Exclusion criteria:

Withdrawal to participation Patients with adenomyosis, submucosal myoma, or endometriosis Patients with abnormal serum lipid profile Patients with underlying diseases or chronic pelvic pain

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 30 letters A and 30 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (Dienogest) or B (Placebo) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind. In this study, the participants and the physician who evaluates the outcomes, are blind. The participants are blinded by using a placebo that is the same as Dienogest, and the physician evaluating the outcomes does not know the treatment group of the participants.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina Ave., Qods Blvd.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2022-09-03, 1401/06/12

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.430

Health conditions studied

1

Description of health condition studied

Dysmenorrhea

ICD-10 code

N94.6

ICD-10 code description

Dysmenorrhea, unspecified

Primary outcomes

1

Description

Dysmenorrhea

Timepoint

Four times (once before the intervention and three times after the intervention) every four weeks

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Estrogen levels

Timepoint

Before the intervention and at the end of the study.

Method of measurement

Serum Estradiol (E2) measurement

2

Description

Premenstrual symptoms

Timepoint

Four times (once before the intervention and three times after the intervention) every four weeks

Method of measurement

Menstrual Distress Questionnaire

3

Description

Dienogest side effects

Timepoint

Four times (once before the intervention and three times after the intervention) every four weeks

Method of measurement

Patient interview

Intervention groups

1

Description

Intervention group: For this group of patients, 0.5 milligrams Dienogest (one-quarter of a tablet produced by the Aburihan pharmaceutical factory named Dinovol) is prescribed twice a day (every 12 hours) from the second day of the patient's mensuration cycles and continues for 12 weeks. Dienogest is the newest generation of progesterone and the only oral progesterone. During the study period, every 4 weeks, the patient is visited regarding dysmenorrhea and drug side effects.

Category

Treatment - Drugs

2

Description

Control group: For this group of patients, one-quarter of a placebo tablet, produced by the Aburihan pharmaceutical factory, is prescribed twice a day (every 12 hours) from the second day of the patient's mensuration cycles and continues for 12 weeks. The placebo tablet is the same as Dinovol. During the study period, every 4 weeks, the patient is visited regarding dysmenorrhea and drug side effects.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Mahbod Ebrahimi

Street address

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahbod Ebrahimi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after unidentified participants.
When the data will become available and for how long
After the manuscript is published.
To whom data/document is available
No limitations.
Under which criteria data/document could be used
Those who are allowed to request to receive non-identifiable personal data or other documents must have a written proposal (including the type of statistical analysis) and the ethics number. any additional analysis must perform under the corresponding author's supervision.
From where data/document is obtainable
Communicate with the corresponding author via email: maeb214@yahoo.com
What processes are involved for a request to access data/document
Any request must be sent through e-mail and accompanied by a proposal with an ethics code under the supervision of Dr. Ebrahimi.
Comments