Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of treatment outcomes of dienogest alone versus dienogest with zinc in endometriosis:single blind clinical-trial

Protocol summary

Study aim
Comparison of treatment results of dienogest alone and dienogest combined with zinc in endometriosis patients

Design
A two-group, single-blind, phase 3 clinical trial will be conducted on 72 patients with endometriosis and randomized using a block randomization method.

Settings and conduct
This study is conducted as a clinical trial at Fatemeh Hospital affiliated with Hamadan University of Medical Sciences. The study subjects in the intervention groups are randomly selected from among women with a confirmed diagnosis of endometriosis (diagnosis by laparoscopy or imaging). Blinding is single-blind and only the outcome assessors and data analysts are unaware.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 45 years. Diagnosis of moderate to severe endometriosis. No use of hormone therapy in the past 3 months. No severe comorbidities (such as liver or kidney disease). Exclusion criteria: Pregnancy or planning to become pregnant during the study. Sensitivity to dienogest or zinc. Unwillingness to continue participating in the study. Inaccessibility of the patient to follow up on treatment results

Intervention groups
This randomized clinical trial (RCT) will be conducted to compare the effects of dienogest alone and dienogest combined with zinc in the treatment of endometriosis. The first group will receive dienogest alone (dose 2 mg daily) orally and the second group will receive dienogest 2 mg daily + zinc (dose 50 mg daily) orally, once daily.

Main outcome variables
Comparison of treatment results of dienogest alone and dienogest combined with zinc in endometriosis patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230522058253N10**
Registration date: **2026-02-05, 1404/11/16**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-05, 1404/11/16**
Update count: **0**

Registration date
2026-02-05, 1404/11/16

Registrant information

Name
neda alimohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0808

Email address
nalimohamadi68@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-02, 1404/11/13

Expected recruitment end date
2026-03-04, 1404/12/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of treatment outcomes of dienogest alone versus dienogest with zinc in endometriosis:single blind clinical-trial

Public title
treatment outcomes of dienogest alone versus dienogest with zinc in endometriosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 45 years. No severe comorbidities (such as liver or kidney disease) No use of hormone therapy in the past 3 months Diagnosis of moderate to severe endometriosis.
Exclusion criteria:
Pregnancy or planning to become pregnant during the study. Inaccessibility of the patient for follow-up of treatment outcome Allergy to dienogest or zinc. Unwillingness to continue participating in the study.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
And using the block randomization method, they will be assigned to two groups A (dienogest alone) and B (dienogest with zinc) using four-blocks. In order to use block randomization, four-blocks are used, which will have 6 blocks in the following order, and each of the blocks will be numbered and will be used for 4 patients, that is, if block number 1 is selected in the lottery, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment A, and the fourth patient will receive treatment B. The fifth patient will be selected again by lottery and randomly from one of the blocks, and the type of treatment will be assigned to the fifth to eighth patients, respectively, based on the block. In the block randomization method, it is possible that a block will be selected more than once in the lottery. In this way, two equal groups of 36 patients are placed in 18 blocks of 4.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the different types of interventions, it is not possible to blind the doctor and the patient. Only the person who ultimately evaluates the patients will be unaware of the type of treatment (single blind).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of hamadan University of Medical Sciences
Street address
Fatemieh hospital, Pastaran Ave.
City
hamadan
Province
Hamadan
Postal code
6517789971
Approval date
2025-07-11, 1404/04/20
Ethics committee reference number
IR.UMSHA.REC.1404.238

Health conditions studied

1

Description of health condition studied
Women with a confirmed diagnosis of endometriosis (diagnosed by laparoscopy or imaging).
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the average pain score of endometriosis patients in the two groups of dienogest alone and dienogest combined with zinc
Timepoint
Group 1: Dienogest alone (2 mg daily dose) orally and Group 2: Dienogest 2 mg daily dose + Zinc (50 mg daily dose) orally, once daily. Both groups will be followed for 6 months (at intervals of 1, 3 and 6 months). Patients will be visited by a gynecologist at monthly intervals to assess pain . At the end of the fourth month, they will be re-evaluated for pain score.
Method of measurement
VAS pain measurement tool

2

Description
Determining the average quality of life score in endometriosis patients in two groups: dienogest alone and dienogest combined with zinc.
Timepoint
Group 1: Dienogest alone (2 mg daily dose) orally and

Group 2: Dienogest 2 mg daily dose + Zinc (50 mg daily dose) orally, once daily. Both groups will be followed up for 6 months (at intervals of 1, 3 and 6 months). Patients will be evaluated by the researcher at monthly intervals for quality of life assessment during gynecological visits. At the end of the fourth month, they will be re-evaluated for quality of life score.

Method of measurement

Endometriosis-related quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women with confirmed endometriosis (diagnosed by laparoscopy or imaging) will be divided into two groups. Group 1: dienogest alone (dose 2 mg daily) orally, once daily. Both groups will be followed for 6 months (at intervals of 1, 3 and 6 months). Patients will be visited by a gynecologist at monthly intervals to assess symptoms and side effects. At the end of the fourth month, they will be re-evaluated for pain score and quality of life.

Category

Treatment - Drugs

2

Description

Intervention group: Women with confirmed endometriosis (diagnosed by laparoscopy or imaging) will be divided into two groups. Group 2: dienogest 2 mg daily + zinc (dose 50 mg daily) orally, once daily. Both groups will be followed for 6 months (at intervals of 1, 3 and 6 months). Patients will be visited by a gynecologist at monthly intervals to assess symptoms and side effects. At the end of the fourth month, they will be re-evaluated for pain score and quality of life.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Maryam Ahmadi

Street address

Pastaran Ave

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7013

Email

nalimohamadi68@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

Street address

Pastaran Ave, Hamedan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7013

Email

nalimohamadi68@yahoo.co

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pastaran Ave

City
Hamadan
Province
Hamadan
Postal code
6517789971
Phone
+98 81 3828 3939
Email
maryam-ahmadi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Maryam Ahmadi
Position
Gynecologist
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Pastaran street- fatemieh hospital
City
Hamadan
Province
Hamadan
Postal code
6517789971
Phone
+98 81 3838 0808
Fax
Email
nalimohamadi68@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Maryam Ahmadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Pastaran Ave
City
Hamadan
Province
Hamadan
Postal code
6517789971
Phone
+98 81 3828 3939
Email
sima_kamkari@yahoo.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