Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effects of levonorgestrel-releasing intrauterine system in reducing pain in women with endometriosis

Protocol summary

Study aim
Assessing the effect of Mirena IUD in reducing pain and preventing progression of endometriosis
Design
Single-group (before and after) non-randomized phase 2-3 clinical trial on 43 patients affected by endometriosis, with pain caused by the disease (no control group, no blinding)
Settings and conduct
The place of the study is the special endometriosis clinic of Imam Reza Hospital in Mashhad. The study population includes all patients with a definite diagnosis of endometriosis through imaging (transvaginal/transrectal ultrasound or MRI) who have pain caused by endometriosis. Blinding is not done in this study.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to endometriosis clinic of Imam Reza Hospital in Mashhad with diagnosis of endometriosis; having pain caused by disease; age of 20-45 years; desire to have contraception; not using NSAID analgesics; body mass index between 18.5 and 27.5 kg/m2. Exclusion criteria: Undiagnosed vaginal bleeding; Suspected malignancy in biopsy; Uterine size greater than 10 weeks of gestation; Submucosal leiomyoma or polyp; septic abortion in the last three months
Intervention groups
Intervention group: 43 patients with endometriosis treated by Mirena IUD.
Main outcome variables
Score of pain based on NPRS criteria

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20141230020486N6**
Registration date: **2024-11-13, 1403/08/23**
Registration timing: **prospective**

Last update: **2024-11-13, 1403/08/23**
Update count: **0**
Registration date
2024-11-13, 1403/08/23

Registrant information
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Leili Hafizi
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-04, 1403/10/15
Expected recruitment end date
2025-07-06, 1404/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effects of levonorgestrel-releasing intrauterine system in reducing pain in women with endometriosis

Public title
The effect of Mirena IUD in reducing pain of

endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with definitive diagnosis of endometriosis through imaging having pain caused by endometriosis Regular menstrual periods (between 25 and 35 days) Not using hormonal therapy for more than 6 months before the study Desire to have contraception Not using NSAID analgesics Body mass index between 18.5 and 27.5 kg/m2 body

Exclusion criteria:

Undiagnosed vaginal bleeding Chronic diseases (eg liver problems, diabetes or pelvic inflammatory disease) History of septic abortion in the last three months Use of hormonal contraception and IUD during the last 3 months Pregnancy or breastfeeding in the last 3 months Suspected malignancy in biopsy Desire to pregnancy Uterine size greater than 10 weeks of gestation Submucosal leiomyoma or polyp History of osteoporosis Coagulopaties or allergy to progestins

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **43**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ghoreshi Bulding, Next to Hoveyzeh Cinema, Daneshgah Ave.

City

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Razavi Khorasan

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Approval date

2024-09-16, 1403/06/26

Ethics committee reference number

IR.MUMS.IRH.REC.1403.141

Health conditions studied

1

Description of health condition studied

Endometriosis disease

ICD-10 code

N80.3

ICD-10 code description

Endometriosis of pelvic peritoneum

2

Description of health condition studied

Endometriosis of rectovaginal septum

ICD-10 code

N80.4

ICD-10 code description

Endometriosis of rectovaginal septum and vagina

Primary outcomes

1

Description

Score of dysmenorrhea, based on the Numeric Pain Rating Scale

Timepoint

Measurement of dysmenorrhea score at the beginning of the study (before the intervention) and 6 months after placement of the mirena IUD.

Method of measurement

Based on the Numeric Pain Rating Scale index

2

Description

Score of dyspareunia, based on the Numeric Pain Rating Scale

Timepoint

Measurement of dyspareunia score at the beginning of the study (before the intervention) and 6 months after placement of the mirena IUD.

Method of measurement

Based on the Numeric Pain Rating Scale index

3

Description

Score of dyschezia, based on the Numeric Pain Rating Scale

Timepoint

Measurement of dyschezia score at the beginning of the

study (before the intervention) and 6 months after placement of the mirena IUD.

Method of measurement

Based on the Numeric Pain Rating Scale index

4

Description

Score of non-cyclic pelvic pain, based on the Numeric Pain Rating Scale

Timepoint

Measurement of non-cyclic pelvic pain score at the beginning of the study (before the intervention) and 6 months after placement of the mirena IUD.

Method of measurement

Based on the Numeric Pain Rating Scale index

Secondary outcomes

1

Description

Cancer Antigen 125

Timepoint

Measurement of Cancer Antigen 125 at the beginning of the study (before the intervention) and 6 months after placement of the levonorgestrel-releasing intrauterine system (mirena).

Method of measurement

Based on serum CA125 protein level test (U/ml)

Intervention groups

1

Description

Intervention group: Placement of 52 mg levonorgestrel-releasing intrauterine system (Mirena IUD) (releasing 20 micrograms of levonorgestrel in 24 hours), made by Bayer Company, Germany, in the uterine cavity of patients with endometriosis on an outpatient setting in the clinic. The IUD can remain in the uterus for up to 5 years.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Endometriosis Clinic, Imam Reza Hospital, Mashhad

Full name of responsible person

Leili Hafizi Lotfabadi

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Ebne Sina Ave.

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Sponsors / Funding sources

1

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Leili Hafizi Lotfabadi

Position

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
All data is potentially shareable after making individuals unidentifiable
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Mention the source
From where data/document is obtainable
Dr. Leili Hafizi / Email: hafizil@mums.ac.ir / Phone: 09153107633
What processes are involved for a request to access data/document
Reply to email within a maximum of one week
Comments