Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of the Effectiveness of Hypnotherapy on Pain Intensity in Endometriosis Patients Treated With Dinogest: A Randomized Controlled clinical trial

Protocol summary

Study aim
Determining the Effectiveness of Hypnotherapy on Pain Intensity in Endometriosis Patients Treated with Dinogest

Design
A Clinical Trial with a Control Group, with Parallel Groups, Randomized on 22 Patients, then After Collecting the Sample (22 people) will be Analyzed and the Final Sample Size will be Calculated.

Settings and conduct
The Interventions will be Performed by a Senior Counseling Student in Midwifery who has a Valid Certificate from the Iranian Clinical Hypnosis Association at the Gynecology Clinic of Shahid Akbarabadi Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Women with Dinogest Endometriosis, Married Women 18-45 Years Old, Complaining of Painful Menstruation or Painful Intercourse or Pelvic Pain, Having a Smartphone and Internet Access ; History of Surgery for Endometriosis, History of Major or Minor Psychiatric Disorder in an Individual or Family, Use of Other Non-Pharmacological Methods, Concomitant Cancer, Treatment of Anxiety or Depression, and Uncontrolled Seizures

Intervention groups
Patients in Both Groups (Control and Intervention) who According to the Standard Treatment of the Gynecologist of Akbarabadi Hospital are Treated with Dienogest in the Amount of one 2 mg Tablet Daily, in the Intervention Group in Addition to Routine Treatment, will Receive Hypnotherapy which Includes 8 Sessions. The First Session will be Held in Person and Individually and the Remaining 7 Sessions will be Held Weekly, Individually, Online (via WhatsApp virtual Network) for 45-30 Minutes, and at the end of Each Session, the Audio Recording File of the Session for Each The Participant of the Intervention Group will be Sent to Perform Hypnosis Exercises at Home at least Twice a Day (for 30 minutes). Control group: 2 mg daily Dienogest tablets

Main outcome variables
Pain; Quality of Life; Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110827007422N4**
Registration date: **2021-09-18, 1400/06/27**
Registration timing: **prospective**

Last update: **2021-09-18, 1400/06/27**
Update count: **0**

Registration date
2021-09-18, 1400/06/27

Registrant information

Name
Zhila Ganji
Name of organization / entity
Mazandaran University of Medical Scinces
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 7342
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zhila.ganji@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Hypnotherapy on Pain Intensity in Endometriosis Patients Treated With Dinogest: A Randomized Controlled clinical trial

Public title
The Effect of Hypnotherapy on Pain Intensity in Endometriosis Patients Treated With Dinogest
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women with Endometriosis (Confirmed by Laparoscopy or Laparotomy and Confirmed by Histology) Treated with Dynogest Married Women 45-18 Years Complaints of Painful Menstruation or Painful Intercourse or Pelvic Pain With a Minimum Score of 5 Cm on a Visual Analog Scale Pain at the Start of Treatment Having a Smartphone Internet Access
Exclusion criteria:
People With a History of Endometriosis Treatment With Surgery (Laparotomy, Llaparoscopy and Hysterectomy) History of Major or Minor Psychiatric Disorder in a First-Degree Individual or Family (Father, Mother, Sister, Brother, Child) People Who Currently Use Other Non-Pharmacological Methods to Reduce Pain (Such as: Yoga, Herbal Medicine, Acupressure, Acupuncture, Traditional Medicine, Biofeedback, etc.) Existence of Concomitant Cancer, Treatment of Anxiety or Uncontrolled Depression and Seizures
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the Fact that the Final Sample Size will be Determined after the Pilot Study, at Present the Number of Final Blocks is Not Known, but the Blocking Method will be Used.The blocks will be TTCC, TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. The numbers will be randomly generated by the RANDBETWEEN command in Excel software in the range 0 to 6. Depending on the production values of one of the blocks (for production number between 0 to 1 CTTC block, for production number between 1 to 2 CTCT blocks and so on) will be selected and samples will be allocated accordingly.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding will be done at the Level of Outcome Assessor and Evaluation at the Level of Analysis. The Person who will Evaluate the Outcome and Analyze the Data does not Know the Status of the Samples and does not Know which Participant is in the Control and Intervention Group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Square
City
Sari
Province
Mazandaran
Postal code
4816715793
Approval date
2021-08-29, 1400/06/07
Ethics committee reference number
IR.MAZUMS.REC.1400.398

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

2

Description of health condition studied
Pain
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Quality of Life
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Women's sexual function
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Before the iIntervention, Immediately After the Intervention, one Month After the Intervention
Method of measurement
VAS Pain Visual Scale Questionnaire

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before the Intervention, Immediately and one Month after the Intervention
Method of measurement
Endometriosis Quality of Life Questionnaire EHP-5

2

Description
Sexual Function
Timepoint
Before the Intervention, Immediately and one Month after the Intervention
Method of measurement
FSFI Women's Sexual Performance Index Questionnaire

Intervention groups

1

Description
Intervention group: In Addition to the Routine Treatment, which Includes 2 mg of Dienogest Tablets Daily, Hypnotherapy in 8 Sessions, the First Session in Person and Individually and the Other 7 Sessions once a Week, Individually, Online (via WhatsApp virtual network) and It will be Held for 30-45 Minutes, and at the end of Each Session, an File Recording of the Session will be Sent to Each Participant in the Intervention Group to Perform Hypnosis Exercises at Home at Least Twice a Day (for 30 Minutes). And Mark the Number of Exercises in the Form that will be provided to them
Category
Treatment - Other

2

Description
Control group: During the Study, Except for the Routine Treatment of 2 mg Dienogest Tablets Daily, no Intervention is Performed only After the Completion of the Research Process, In Order to Observe Research Ethics, Hypnotherapy Sessions will be Offered to the Subjects of the Control Group of the Recorded Files.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi Hospital Health Centers
Full name of responsible person
Dr Roya Shahriyaripoor
Street address
Molavi St., not far from Molavi intersection, Ferdows Garden Station
City
Tehran
Province
Tehran
Postal code
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Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Akbar Hedayatizadeh Omran
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Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Avenue
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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Roja Shahriyaripoor

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Nasibeh Nursing and Midwifery Faculty, Vesal Shirazi Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Jila Ganji

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

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Position

Masters Student

Latest degree

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Other areas of specialty/work

Midwifery

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Phone

+98 11 3337 4750

Email

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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