Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of CGRP neuropeptide levels in patients with endometriosis pain treated with dienogest

Protocol summary

Study aim
Comparative study of CGRP neuropeptide levels in patients with endometriosis-induced pain treated with Dinoest

Design
Pain is measured with VAS and a basal serum sample is prepared for the peptide and then, according to the physician's diagnosis, they receive 2 mg orally from one of the dinogest options for pain medication. 6 months later, serum samples are collected for CGRP measurement. Be brought. This information will be provided to the patient as the research information is useful in the future treatment process.

Settings and conduct
Patients with endometriosis who did not receive hormone therapy 3 months ago were referred to Rasoul Hospital and have pain due to the disease. Blood is prepared before using dinogest and 6 months after serum consumption, and serum CGRP level and pain are measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Women aged 18-44 years with pain and suspected endometriosis Do not take hormonal drugs containing estrogen or progesterone for three months No pregnancy Absence of genital or breast cancers No abnormal vaginal bleeding No breastfeeding for 3 months Do not use housing during the last week No surgery in the last 3 months No liver problems No strong history of venous thrombosis or embolism Body mass index 5 / 18-26 Exclusion criteria for the endometriosis group include: Has a history of any genital cancer in the pelvic area Hormone therapy for the past 3 months Suffering from a variety of systemic diseases History of endometrial destruction by thermal balloon or resectoscope

Intervention groups
Patients take dinogest for 6 months.

Main outcome variables
intensity and frequency of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220313054264N1**
Registration date: **2022-06-12, 1401/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-12, 1401/03/22**
Update count: **0**

Registration date
2022-06-12, 1401/03/22

Registrant information
Name
Marziyeh Ajdary
Name of organization / entity
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+98 21 6650 9283
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A comparative study of CGRP neuropeptide levels in patients with endometriosis pain treated with dienogest

Public title
A comparative study of CGRP neuropeptide levels in patients with endometriosis pain treated with dienogest
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-44 years with pain and suspected endometriosis Do not take hormonal drugs containing estrogen or progesterone for three months No pregnancy Absence of genital or breast cancers No abnormal vaginal bleeding No breastfeeding for 3 months Do not use housing during the last week No surgery in the last 3 months No liver problems No strong history of venous thrombosis or embolism Body mass index 5 / 18-26
Exclusion criteria:
Has a history of any genital cancer in the pelvic area Hormone therapy for the past 3 months Suffering from a variety of systemic diseases History of endometrial destruction by thermal balloon or resectoscope
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **10**
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 Iran University of Medical Sciences
Street address
Sattar Khan - Hazrat Rasool Akram Hospital
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2022-06-01, 1401/03/11
Ethics committee reference number
IR.IUMS.REC.1401.219

Health conditions studied

1

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

Primary outcomes

1

Description
Intensity of pain
Timepoint
3 months and 6 months later
Method of measurement
Vas score questionnaire

2

Description
The amount of CGRP neuropeptide
Timepoint
6 months later
Method of measurement
ELISA device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with endometriosis with pain, according to the doctor's diagnosis for drug treatment of pain Dinogen 2 mg per day orally (tablets) (Iran Hormone Company) once a day for 6 months and assess pain and level The CGRP marker is evaluated before and after taking the drug.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital

Full name of responsible person
Dr Marziyeh Ajdary
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Hossein Keyvani-Vice Chancellor for Research and Technology, Iran University of Medical Sciences
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Marziyeh Ajdary-Iran University of Medical Sciences
Position
assistant professor
Latest degree
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Other areas of specialty/work
Reproductive Biology
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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
Yes - There is 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
Not applicable
Title and more details about the data/document
Part of data like the main outcome or the same will be shared
When the data will become available and for how long
Access after 6 months after publication
To whom data/document is available
Data will be available for all researchers
Under which criteria data/document could be used
It is important for further research and identification of markers in reducing patients' pain that can be used later in the pharmaceutical industry.
From where data/document is obtainable
For receiving data please be contacted with ajdari.m@iums.ac.ir
What processes are involved for a request to access data/document
limitless
Comments