

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation the efficacy of D-Chiro-Inositol in pain relief in endometriosis

Protocol summary

Study aim

Considering the prevalence of endometriosis and its debilitating symptoms and complications, which can affect the psychosocial parameters of a society by reducing the quality of life. By using drugs such as di-chiro-inositol, it is possible to help reduce the pain and complications of this disease by reducing the production of estrogen.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients referring to Taleghani Hospital's gynaecology Clinic, receiving drug packages, patients and caregivers are blinded

Participants/Inclusion and exclusion criteria

Criteria for entering : age : between 20 and 40 years, refusal to receive other standard treatments pelvic pain that has been present for at least the last three months, diagnosis of endometriosis systemic estradiol higher than 90 pg/ml in the first 4 days after the end of the period, consent to start the plan and exclusion criteria from the plan: BMI>30), history of diabetes, history of tumors Secretion, use of hormones or inositol within 6 months before starting the study, use of other drugs, especially (OCP and...), any disease that interferes with the use of di chiro inositol, pregnancy/lactation

Intervention groups

In this RCT study, patients referring to the gynecology clinic, whose endometriosis has been confirmed using transvaginal ultrasound, will be determined and randomly divided into two equal groups. The goals and results obtained are discussed and an attempt is made to obtain the consent of the patients to participate in the study. A written consent is obtained from the patients who agree to participate. Then, the case and control groups are given separate medication packages.

Main outcome variables

dyspareunia; dysmenorrhea; pelvic pain; age; BMI; dyschezia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230111057113N1**

Registration date: **2023-02-23, 1401/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**

Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Samaneh Esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4435 2355

Email address

dresmaeili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-21, 1401/12/02

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of D-Chiro-Inositol in pain relief in endometriosis

Public title

Evaluation the efficacy of D-Chiro-Inositol in endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 40 years old
Diagnosis of endometriosis
Refusal to use other standard therapies
Systemic estradiol >90 pg/ml during the first 4 days after the end of menstrual cycle.
informed consent to entry
Pelvic pain that has been present for at least three months

Exclusion criteria:

Diagnosis of secreting tumors
previous history of Diabetes Melitus
BMI>30
Taking hormones or inositol within 6 months before starting the study
Using other drugs, especially (OCP and...) Any disease that interferes with the use of D-chiroinositol

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly given a sealed envelope containing medicine

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be randomly divided into two equal groups. The patients are discussed about the research plan and the method, the goals and the results obtained and An attempt is made to obtain the consent of the patients to participate in the study. Written consent is obtained from patients who agree to participate and Then they will be divided into case and control groups. In a random and double-blind manner, the medicine packages will be distributed by the doctor between the two groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Taleghani hospital, Next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St, Yemen St, Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.751

Health conditions studied

1

Description of health condition studied

Endometriosis is characterized by the presence of endometrial and stromal tissue outside the uterine cavity

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Pelvic pain

Timepoint

At the beginning of the study, one month after the start of treatment, 6 months after the start of treatment

Method of measurement

VAS score

Secondary outcomes

1

Description

Pelvic pain

Timepoint

At the beginning of the study, one month after the start of treatment, 6 months after the start of treatment

Method of measurement

VAS score

2

Description

Dyspareunia

Timepoint

At the beginning of the study, one month after the start of treatment, 6 months after the start of treatment

Method of measurement

Vas score

3

Description

Dysmenorrhea

Timepoint

At the beginning of the study, one month after the start of treatment, 6 months after the start of treatment

Method of measurement

Vas score

4

Description

Dyschezia

Timepoint

At the beginning of the study, one month after the start of treatment, 6 months after the start of treatment

Method of measurement

Vas score

Intervention groups

1

Description

Intervention group: two tablets containing 1200 mg of DCI and 120 mg of alpha-lactalbumin for the first month and 600 mg of DCI and 60 mg of alpha-lactalbumin for the next 5 months.

Category

Treatment - Drugs

2

Description

Control group: Control group: tablets containing 600 mg of maltodextrin daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital

Full name of responsible person
Sagar Salehpour

Street address

Taleghani Hospital ,Next to Shahid Beheshti University of Medical Sciences,- Shahid Arabi St, Yemen St, Shahid Chamran Highway,Tehran

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Phone

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Email

dresmaeili@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

Street address

Taleghani Hospital,Next to Shahid Beheshti University of Medical Sciences,Shahid Arabi St,Yemen St ,Shahid Chamran Highway ,Tehran

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

20

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Samaneh Esmaeili

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Taleghani Hospital, Next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St, Yemen St, Shahid Chamran Highway, Tehran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Samaneh Esmaeili

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

For scientific studies and therapeutic use

From where data/document is obtainable

Samaneh Esmaeili.dresmaeili@gmail.com

What processes are involved for a request to access data/document

Within a month of receiving the email

Comments