# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Evaluation the efficacy of D-Chiro-Inositol in pain relif 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 relif 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**
،ehran

**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
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Fax**
+98 21 2243 2570
**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
**City**
tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Fax**
+98 21 2243 2570
**Email**
dresmaeili@gmail.com
**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
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Email**
dresmaeili@gmail.com

## 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**
Gynecology and Obstetrics
**Street address**
Taleghani Hospital,Next to Shahid Beheshti University of Medical Sciences,Shahid Arabi St,Yemen St ,Shahid Chamran Highway ,Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Email**
dresmaeili@gmail.com

## Person responsible for updating data

**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
**City**
Tehran
**Province**
Tehran
**Postal code**
1985711151
**Phone**
+98 21 2243 2560
**Email**
dresmaeili@gmail.com

## 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**