# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Efficacy of Proscure capsule on dysmenorrhea in known cases of endometriosis

### Protocol summary

**Study aim**
The efficacy of Proscure on dysmenorrhea in endometriosis

**Design**
It is a double-blind clinical and random astrology. Phase Three Clinical Studies. Women aged 20-45 years referred from a specialized endometriosis clinic by a gynecologist with a complaint Pain. Patients are divided into intervention and control groups based on a table of random numbers (prepared by a statistician). Drugs and placebo are given to patients in thirty packs for three months Becomes. Two a day, one in the morning, one at night for 90 days.

**Settings and conduct**
Rasoul Akram Hospital is a traditional medicine clinic. Drugs and placebo are given to patients in thirty packs for three months Becomes. At the beginning of the study, the VAS questionnaire for patients' pain (including dysmenorrhea, dyspareunia, and chronic non-menstrual pelvic pain and pain) was filled out and once at the end. 30 days of treatment and once at the end of 60 days and then after 90 days) at the end of the study (the questionnaire is filled out again). The endometriosis clinic will be referred.

**Participants/Inclusion and exclusion criteria**
Women aged 20 to 45 years Definitive diagnosis of endometriosis Not intending to become pregnant Degree of pain caused by more or less alignment No breastfeeding Lack of emergency medical care Referral from a gynecologist

**Intervention groups**
Proscure in intervention group Placebo in control group

**Main outcome variables**
Dyspareunia Dysmenorrhea Quality of Life Pelvic pain

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20211201053241N1**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

**Registration date**
2022-01-01, 1400/10/11

**Registrant information**

**Name**
Elham Akhatri

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 5563 9667

**Email address**
eli.akhtari@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-12-21, 1400/09/30

**Expected recruitment end date**
2022-06-20, 1401/03/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Efficacy of Proscure capsule on dysmenorrhea in known cases of endometriosis

**Public title**

Efficacy of Proscure on dysmenorrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Definite diagnosis of Endometriosis Gynecological refer VAS bigger than or equal 3 No need to emergency management Age between 20-45

**Exclusion criteria:**

Wish to pregnancy in 3 months later breast feeding need to emergency no attempt to herbal medicine

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, people are divided into two groups: moderate and severe. Then in each category, randomization is done by block method. First, 4 blocks of A and B are written. Then, with the help of a random number table (Excel program), the blocks are randomly selected and lined up side by side to complete the desired sample size. A random list is provided to the person performing the illness. The patient and the person receiving the disease are not aware of the type of drug A and B, and the placebo drug is similar in appearance. Also, the data analyzer is not aware of types A and B (three-way blind study). For allocation concealment, letter envelopes are used in the package so that the number of the person referring to the envelope and the type of medicine he should receive is written in the envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The table of random numbers prepared by a respected statistical expert is available to the researcher. The medicine and placebo packs are packaged in a similar way and the table numbers are repeated and recorded on them and the consulting pharmacist is in the process of this packaging. In this way, with the arrival of the patient who fills in the forms, the pack is followed by the relevant number delivered.

**Placebo**

Used

**Assignment**

Parallel

**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**

University of Persian Medicine, Behesht Street, Vahdat eslami Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1114733311

**Approval date**

2021-11-21, 1400/08/30

**Ethics committee reference number**

IR.IUMS.REC.1400.783

## Health conditions studied

### 1

**Description of health condition studied**

Endimetriosis

**ICD-10 code**

N80.0

**ICD-10 code description**

Endometriosis of uterus

## Primary outcomes

### 1

**Description**

Dysparunia based on VAS questionare

**Timepoint**

The beginning of the study and then the end of the study at the end of three months of treatment

**Method of measurement**

VAS questionaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Women 20 to 45 years old with dysmenorrhea due to endometriosis; The intervention is the prescription of Proscore drug produced by Gol Daroo company that the patient consumes morning and night in clean days. First, the pain and quality of life questionnaire is filled in by the therapist, then the package containing the medicine is delivered, the patient is visited every 4 weeks until the three menstrual cycles,

and finally the questionnaires will be filled in again.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Women 20 to 45 years old with dysmenorrhea due to endometriosis; The intervention is the prescription of Proscore drug produced by Gol Daroo company that the patient consumes morning and night in clean days. First, the pain and quality of life questionnaire is filled in by the therapist, then the package containing the medicine is delivered, the patient is visited every 4 weeks until the three menstrual cycles, and finally the questionnaires will be filled in again.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Rasool Akram Hospital

**Full name of responsible person**
Elham Akhtari

**Street address**
Persian Medicine School, Behasht Ave. Tehran, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Majid Dadmehr

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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**
Elham Akhtari

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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Persian Medicine school, Behesht Ave, Tehran, Iran

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## Person responsible for scientific inquiries

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

All data can be shared after identifying individuals.

**When the data will become available and for how long**

Access starts six months after printing the results

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

For sample use in larger studies

**From where data/document is obtainable**

Email the scientific interface of the project called Elham Akhtari

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

An email will be sent and it will be done within a week.

**Comments**