

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The evaluation of therapeutic effect of dopamine agonist (bromocriptine) on endometrioma size

Protocol summary

Study aim

Assessment of the effect of bromocriptine plus medroxyprogesterone compared with medroxyprogesterone plus placebo on size and clinical symptoms associated with endometrioma.

Design

a double-blinded, phase 2 randomized clinical trial with parallel groups, 60 patients, with ovarian endometrioma, will be randomly assigned into two groups of medroxyprogesterone with Bromocriptine and medroxyprogesterone with placebo via the block randomization method.

Settings and conduct

This study will be carried out on 60 patients with ovarian endometrioma at Shiraz Madar o Kodak Hospital, After random allocation, They will receive medroxyprogesterone with Bromocriptine and medroxyprogesterone with placebo twice daily for 3 months. Endometrioma size, Dysmenorrhea, Dyspareunia will be compared before and at the end of three months. The researcher and statistician will be unaware of how the interventions are allocated.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Having informed consent, definitive diagnosis of endometrioma, Exclusion criteria include: patients with hyperprolactinemia, People with coagulation disorders, who have contraindications to medroxyprogesterone

Intervention groups

intervention group: received medroxyprogesterone 20 mg with Bromocriptine 1.25 mg twice daily for 3 months. Control group: received medroxyprogesterone 20 mg with placebo twice daily for 3 months.

Main outcome variables

Endometrioma size, Dysmenorrhea, Dyspareunia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140802018655N6**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Tahereh Poordast

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 2365

Email address

poordast@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of therapeutic effect of dopamine agonist (bromocriptine) on endometrioma size

Public title

The effect of bromocriptine on endometrioma size

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A definitive diagnosis of endometrioma

Exclusion criteria:

patients with hyperprolactinemia People with coagulation disorders who have contraindications to medroxyprogesterone

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size was 60 participants (30 people in each group). The block randomization method was developed by an epidemiologist collaborator using version 13 of Stata software. To conceal the random allocation process, 60 treatment cards were written in sequential order, then the cards were placed in sealed envelopes. On each envelope, a random code was written with no sequences that only the methodologist was aware of the code. When the physician announced a patient's eligibility, the methodologist provided the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who evaluated the final outcomes was unaware of the random allocation process and the type of treatment performed. Data were analyzed by a statistical expert who was separated from the study process and unaware of all the processes performed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.SUMS.REC.1399.979

Health conditions studied**1****Description of health condition studied**

Endometrioma

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes**1****Description**

endometrioma size

Timepoint

Before transplantation and at the end of 3 months

Method of measurement

Ultrasonography

2**Description**

Pain pelvic

Timepoint

Before transplantation and at the end of 3 months

Method of measurement

VAS test

Secondary outcomes**1****Description**

Dysmenorrhea

Timepoint

Before transplantation and at the end of 3 months

Method of measurement

VAS test

2**Description**

Dyspareunia

Timepoint

Before transplantation and at the end of 3 months

Method of measurement

VAS test

Intervention groups

1

Description

Intervention group: Received medroxyprogesterone 20 mg with Bromocriptine 1/25 mg twice daily for at least 3 months

Category

Treatment - Drugs

2

Description

Control group: Received medroxyprogesterone 20 mg twice daily with placebo for at least 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Madar o Kodak Hospital

Full name of responsible person

Tahereh Poordast

Street address

Madar o Kodak Hospital, Emam Reza Boulevard

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

Email

ta.poordast@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

poshtoff@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Tahereh Poordast

Position

Fellow ship of Infertility and Laparoscopy

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Madar o Kodak Hospital, EmamReza Boulevard

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 4596

Email

ta.poordast@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Tahereh Poordast

Position

Fellow ship of Infertility and Laparoscopy

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Madar o Kodak Hospitall, Emam Reza Boulevard

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3233 2365

Email

ta.poordast@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Parizad nassirkandi

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Madar o Kodak Hospitall, EmamReza Boulevard

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3233 2365

Email

parizad116@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

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

Title and more details about the data/document

Study data is accessible by observing moral points of view on the confidentiality of patient information.

When the data will become available and for how long

Immediately after the publication of the article

To whom data/document is available

Gynecology specialists in coordination with the presenter

Under which criteria data/document could be used

Meta-analysis is allowed on the data of this study.

From where data/document is obtainable

Dr.Tahereh Poordast, Madar o Kodak Hospital, Emam Reza Boulevard, Shiraz, Iran , Email: ta.poordast@yahoo.com

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

After one year of publishing the article and publishing the results, those who need the data of this study could apply via email.

Comments