Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of sildenafil on dysmenorrhea in patients with endometriosis compared to placebo

Protocol summary

Study aim

Evaluation of the degree of dysmenorrhea of patients with endometriosis before and after treatment with sildenafil compared to placebo; Excessive Intake of analgesia in Endometriosis Dysmenorrhea treated with Sildenafil compared to placebo

Design

Pragmatic, community based, parallel group, double blind, randomized controlled trial.The study population of 40 patients suffering from endometriosis disorder is classified into two groups according to the Randomization table.

Settings and conduct

The setting is Arash Women's Hospital . Oral sildenafil at the dose of 100mg and placebo are given to the patients of two groups daily in the first three days of the cycle, and the degree of change in pain is compared between two groups. To hide the random allocation process, 40 cards containing the name of treatments will be prepared. Then the cards will be placed inside sealed envelopes and the methodologist will give the drug to the patients accordingly. Surgeon, patient, person who assesses the consequences and analyzer the data are blind to the treatment provided to each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with moderate to severe endometriosis dysmenorrhea. Exclusion criteria: people who take Nitrogelycerin or any hormonal therapy, people with high or low blood pressure, PID, ovarian cyst, non-cyclic pelvic pain, malignancy, acute coronary syndrom and acute ocular problem

Intervention groups

Intervention group: oral sildenafil 100mg was administered daily from the first day to the third day of the menstrual period. Control group: Placebo was administered in this group.

Main outcome variables

Primary outcome: The dysmenorrhea change rate
Secondary outcome: The amount of pain killer use during the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140227016765N5**
Registration date: **2018-10-26, 1397/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-26, 1397/08/04**
Update count: **0**

Registration date

2018-10-26, 1397/08/04

Registrant information

Name

Zahra Tavoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 5342

Email address

ztavoli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical science.international campus

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of sildenafil on dysmenorhea in patients with endometriosis compared to placebo

Public title

Effect of Sildenafil on Endometriosis dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with moderate to severe endometriosis suffer from dysmenorrhea, They are between 18 and 45 years old They were diagnosed with ultrasound

Exclusion criteria:

People who take nitroglicerine during study People who have used any hormonal medication People with hepatorenal disease People with pelvic pain non relevant to menstural cycle People with pervious MI or CVA People with abnormal blood pressure People with PID People with malignancies People with acute eye problem

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation list for patients is solely available to the epidemiologist. To hide the random allocation process, 40 card sequences of the treatments will be written accordingly, and then the cards will be placed inside sealed envelopes. On each packet, 10-digit code is written randomly and without any order .This is the patient identification number that only the methodologist will be aware of. When the surgeon announces the eligibility of a patient, the methodologist will provide the surgeon with one of the packets.

Blinding (investigator's opinion)

Double blinded

Blinding description

The surgeon and the patients shouldn't be aware of the type and treatment process they are seeking. Also, the person evaluating the outcomes is the third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Medicine; Tehran University of Medical Sciences

Street address

School of Medicine- Tehran University of Medical Sciences- 16 Azar St- Keshavarz Blvd-Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.064

Health conditions studied

1

Description of health condition studied

endometriosis

ICD-10 code

N80

ICD-10 code description

endometriosis

Primary outcomes

1

Description

pain

Timepoint

Before and 1, 2 and 3 hours after the intervention

Method of measurement

VAS questionnaire

Secondary outcomes

1

Description

The amount of pain-relieving use during the study

Timepoint

At the end of the study

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: using daily sildenafil, 100 mg tablet, during 3 days of menstrual cycle
Category
Treatment - Drugs

2

Description
Control group: using daily placebo tablet, similar to sildenafil, during 3 days of menstrual cycle
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's Arash hospital
Full name of responsible person
Zahra Tavoli
Street address
No.116, 162 alley. Baghdarnia St, Farjam St, Bagheri highway,Tehranpars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Tehran University of Medical Sciences -Ghods street-Keshavarz blvd-Tehran -Iran
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Grant name
First published ISI article grant
Grant code / Reference number
96-03-30-35290
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciencers
Full name of responsible person
Zahra Tavoli
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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