Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of the effect of administration of hormonal contraceptives (OCP) with vitamin D3 supplements on the sexual dysfunction in women with polycystic ovary syndrome: A randomized double-blind placebo-controlled clinical triall

Protocol summary

Study aim

Determination of the effect of concomitant administration of hormonal contraceptives (OCP) with vitamin D3 supplements on sexual dysfunction (MDD) in women with polycystic ovary syndrome.

Design

Considering that no study has been done on the subject of the research and the study has a 6 months' follow-up, there is no possibility of doing a preliminary study prior to the main study. With 95% confidence and 90% test power, the number of samples in both groups equal to 31.08 which means 32 participants in each group, and with a 10% drop rate, 35 people participate in both groups with a total number of 70 participants.

Settings and conduct

First, 70 women aged 18-40 years old with PCOS, sexual dysfunction and vitamin D3 deficiency will be divided into two equal groups of experimental group and control group. Each group will receive 50,000 UI vitamin D3 pearl per week for up to 12 weeks. Patients in the intervention group will take contraceptive pills (OCP) for 3 months (21 days each month) along with vitamin D3 pearl, and those who are in the control group will take placebo with the exact same appearance and administration order of contraceptive pills for three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age: 18-40 years Diagnosis of Polycystic Ovary Syndrome Sexual dysfunction Absence of chronic diseases Women with vitamin D3 deficiency Absence of depression No infertility based on patient's statements Using condom as a contraceptive method Exclusion criteria People who show side effects due to medication consumption

Intervention groups

People who are in the experimental group will receive contraceptives (OCP) for 3 months along with vitamin D3 Pearl.

Main outcome variables

Considering that vitamin D3 is likely to be useful in improving female sexual function, this study aims to investigate the synergistic effect of OCP with vitamin D3 pearls in women with PCOS.

General information

Reason for update

Due to content modification

Acronym

IRCT registration information

IRCT registration number: **IRCT20150905023897N3**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-14, 1403/03/25**
Update count: **1**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Dr. Shahideh Jahanian Sadatmahalleh

Name of organization / entity

Tarbiat Modares University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-01-20, 1397/10/30
Expected recruitment end date
2019-04-18, 1398/01/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effect of administration of hormonal contraceptives (OCP) with vitamin D3 supplements on the sexual dysfunction in women with polycystic ovary syndrome: A randomized double-blind placebo-controlled clinical triall

Public title
Assessment of the effect of contraceptive pills on the treatment of sexual dysfunction in women with polycystic ovary syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
) Iranian women age 18- 404 years , 2) PCOS based on Rotterdam criteria (19), 3) women having Vitamin D3 level less than 20 ng/ml (base on the test), 4) women having sex in the last month, and 5) women who used non-hormonal contraceptives three months before the start of the study
Exclusion criteria:
included having the history of side effects (such as headache, vomiting from OCP), chronic diseases, including diabetes mellitus, hypertension, Vascular-Thrombi-Embolism (VTE), and thyroid, having the history for sterility, having no history of depression based on Beck Depression Inventory (BDI) questionnaire, having intention to conceive in near future, no need for OCP treatment, the having no history of Cushing's syndrome, adrenal hyperplasia, and adrenal tumor.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In case of vitamin D3 deficiency (less than 20 ng/ml) (20), all participants were randomly divided into two equal groups (A and B) using a random number table, where each selected number was randomly assigned to a group. became This work was done until the number of people in each group was completed. The researcher had no authority to change the status of the assignments or predict the entry of people into any group. Random concealment was performed by a third party who did not participate in the other phases of the intervention
Blinding (investigator's opinion)
Double blinded
Blinding description
the researcher and the patients will be unaware of how participants are treated and grouped. For this purpose, the OCP and placebo are codified by the scientific expert of the drug manufacturer (Iran Hormone Company). The main researcher treats patients double-blindly according to the codes of drug packets. The code of the drug packet is recorded on the form of individual information, and the researcher who tracks and completes the information form will not be aware of the type of treatment.
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tarbiat Modares University of Medical Sciences
Street address
Tarbiat Modares University., Bridge Nasr., Jalale Ale Ahmad Ave
City
Tehran
Province
Tehran
Postal code
1411713116
Approval date
2018-12-18, 1397/09/27
Ethics committee reference number
IR.MODARES.REC.1397.169

Health conditions studied

1

Description of health condition studied
Polycystic Ovary Syndrome
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Sexual Dysfunction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual Fanction Score obtained in the Female Sexual Function Index (FSFI) questionnaire
Timepoint
At the start of the study and 3 and 6 months from the start of the treatment
Method of measurement
Female Sexual Function Index (FSFI) questionnaire

2

Description
The level of vitamin D 3 in the blood
Timepoint
At the start of the study and 3 and 6 months from the start of the treatment
Method of measurement
Biochemical examination of blood

Secondary outcomes

empty

Intervention groups

1

Description
LD combined oral contraceptive pills produced by Iran Hormone company are consumed for 3 months, 21 days each month from the second day of the menstrual period, then the medication is not taken for 7 days, and then its consumption will start over again. Pills are taken for up to 3 menstrual periods.
Category
Treatment - Drugs

2

Description
Taking pills of the same color, shape and size (placebo) with LD, which completely has no effect, produced by Iran Hormone company for 3 months, 21 pills each month from the second day of menstruation, and then the medication is not taken for 7 days. Then its consumption start will start again. Pills are taken for up to 3 menstrual periods.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hasan Mojtaba Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
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pres@modares.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
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

Tarbiat Modares University

Full name of responsible person

D Shahideh Jahanian Sadatmahale

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome of the study

When the data will become available and for how long

1400

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Use for further research in the future

From where data/document is obtainable

Email Addressing Responsible for Study

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

Submit a request to study and follow up

Comments