Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of wet-cupping on calf muscles on improving amenorrhea and oligomenorrhea in patients with polycystic ovary syndrome (PCOs)

Protocol summary

Study aim
Determining the Effect of wet-cupping on calf muscles Improvement of Amenorrhea and Oligomenorrhea in Patients with Polycystic Ovary Syndrome

Design
The clinical trial with a control group, with parallel groups, without blinding, Block Randomization, phase 3 will be completed on 92 patients. RAS software is used for block randomization.

Settings and conduct
The study is conducted on two control and intervention groups in designated locations (Mahdieh Hospital in Tehran and Shariat Panahi Health College of Shahid Beheshti School of Traditional Medicine). Both groups were given two 500 mg tablets of metformin daily for three months. For the intervention group, once wet-cupping on calf muscles is performed on both legs.

Participants/Inclusion and exclusion criteria
Inclusion: Polycystic ovary women with menstrual disorders aged 18-35 years and have menstrual cycles of at least 60 days in the last year. Exclusion: Individuals taking metformin or hormonal drugs including herbs and phytoestrogens in the past three months, BHCG positive or lactating women, people with coagulation disorder and anemia

Intervention groups
Two intervention groups will be treated with metformin and one time wet-cupping on calf muscles And the control group will only receive three months of metformin treatment.

Main outcome variables
Frequency of menstrual cycle

General information

Reason for update

Acronym
Pcos

IRCT registration information
IRCT registration number: **IRCT20210809052118N1**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**
Update count: **0**

Registration date
2023-09-13, 1402/06/22

Registrant information

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Leila Goodarzi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-21, 1402/08/30

Expected recruitment end date
2024-11-20, 1403/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of wet-cupping on calf muscles on improving amenorrhea and oligomenorrhea in patients with polycystic ovary syndrome (PCOs)

Public title

Effect of wet-cupping in treatment oligomenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with polycystic ovarian- age between 18 and 35 with menstrual disorder-who have menstrual cycles of at least 60 days in the last year.

Exclusion criteria:

Patients using metformin or every hormonal drugs, including herbal and phytoestrogens, in the last three months Positive BHCG titer or lactating women People with coagulation disorders and anemia

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done in a non-random, easy way (available sample) and the classification of samples to be assigned to treatment is done in a Block randomization. In other words, people are randomly assigned to the treatment and control groups with equal numbers. The randomization unit is considered individual. RAS statistical software was used as a block randomization tool.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The specialized committee of ethics in biomedical research

Street address

Shahid Beheshti University of Medical Sciences, No.2, Aarabi St., Daneshjoo Blvd., Velenjak, Tehran, Iran

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Province

Tehran

Postal code

1985717443

Approval date

2023-04-30, 1402/02/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.069

Health conditions studied

1

Description of health condition studied

Polycystic Ovarian Syndrom

ICD-10 code

E28.0

ICD-10 code description

Polycystic Ovarian Syndrom

Primary outcomes

1

Description

Frequency of menstrual cycle

Timepoint

First day and weeks 2, 4, 6, 8, 10, 12

Method of measurement

Asking the patient

Secondary outcomes

1

Description

Length of bleeding period

Timepoint

The first day and weeks 2، 4، 6، 8،10،12

Method of measurement

Ask the patient based on the number of days of bleeding

2

Description

The amount of excess hair(hirsutism)

Timepoint

The first day and weeks 4، 8، 12

Method of measurement

the Freeman Galloway chart

3

Description

Quality of life of patients with polycystic ovary syndrome

Timepoint

The first day and weeks 4، 8، 12

Method of measurement

PCOSQ-50 Questionnaire

Intervention groups

1

Description
Intervention group: Performing cupping of both legs once and on the 26th day of menstrual cycle- At first, the patient will be given the necessary advice about observing the necessary pre-cupping, such as food precautions. The patient sits on a chair next to the bed, the position of the leg cupping that the posterior-lateral part of the leg and the leg is equal to one foot of the hand above the outer ankle, with the cup, connected to the suction cup. The suction takes a few seconds and 30 times. Repeated cupping before cupping causes partial anesthesia and reduces the amount of pain caused by razor. Then، by observing the sterile tips with a bistorial blade No. 11 along the skin lines (almost oblique)، about 10 to 15 subtle superficial incisions are made on the epidermis and dermis surface. The cupping cup is placed again in the area and with three re-suction in it, excess blood is removed. At the end the area is bandaged after sterilization and recommendations are given for care.

Category
Treatment - Other

2

Description
Control group: Two groups receive 500 mg of metformin twice daily for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahdieh Hospital

Full name of responsible person
Shahrzad Zadeh Modarres

Street address
Boroujerdi St., Shishegar Khaneh St., Fadaiyan Eslam St., Shoosh Sq., Heran

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2

Recruitment center

Name of recruitment center
Shariat Panahi Health School، Shahid Beheshti School of Traditional Medicine

Full name of responsible person
Dr. Mozhgan Tansaz

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No. 8, Shams Alley, in front of Tovanir,Vali Asr St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Mojgan Tansaz
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Associate
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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
Yes - There is 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
Yes - There is 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
The main result and some specific goals are published. Including: the number of menstrual cycles as The main result of the study and the effect of some specific goals such as (increasing the length of the bleeding period - improving the Quality of Life - bleeding in the next month). Confidentiality of information is maintained. Personal information is not published. Only information related to primary and secondary outcomes will be used and shared for analysis.
When the data will become available and for how long
6 months after the publication of the article, the data will be published.
To whom data/document is available
Students and professors of universities of medical sciences and scientific institutions affiliated to universities and the Ministry of Health and Medical Education
Under which criteria data/document could be used
The reasons for using the data it is necessary to obtain the source for the purpose of use the request and signature of the responsible official of the requesting institution
From where data/document is obtainable
The scientific officer of the project- Correspondence to the declared e-mail tansaz_mojgan@yahoo.com

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

Sending a written request with the signature of the official of the requesting institution to the e-mail address of the scientific officer of the project - confirmation of the Requirements to be met (obligation to mention the source) - checking the request and sending the data within a maximum of one month

Comments