

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Leila Goodarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2234 4877

Email address

leila_goodarzi02ir@yahoo.com

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

City

Tehran

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., Fadaian Eslam St., Shoosh Sq., Heran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

+98 21 5506 2627

Email

mahdiyh_hospital@sbmu.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax

+98 21 8879 5008

Email

sitm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Zali

Street address

Shahid Beheshti University of Medical Sciences, Aarabi St., Daneshjoo Blvd., Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717444

Phone

+98 21 23871

Email

info@sbmu.ac.ir

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

Full name of responsible person
Mojgan Tansaz

Position
Associate

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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

City
Tehran

Province
Tehran

Postal code
1516745811

Phone
+98 21 8877 3521

Email
tansaz_mojgan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shahzad Zadeh Modares

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Boroujerdi St., Shishegar Khaneh St., Fadaian Eslam
St., Shoosh Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1185817311

Phone
+98 21 5631 4935

Fax
+98 21 5506 2627

Email
mahdiyeh_hospital@sbm.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mojgan Tansaz

Position

Associate

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Address: No. 8, Shams Alley, Valiasr St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
141556153

Phone
+98 21 8877 3521

Email
tansaz_mojgan@yahoo.com

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