

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the efficacy of wet cupping and blood donation on decrease of menstruation period and insulin resistance in polycystic ovarian syndrome (PCOS)

Protocol summary

Summary

The aim of this study is comparison the effect of calves wet-cupping with blood donation on decrease of menstruation period and insulin resistance with Pcos. This study is randomized clinical trial and is single central trial. Study group is the women with Pcos according to National Institute of Health criteria. Sample size is 60 members that will divided in two groups with 30 participants. Calves wet-cupping or 20cc cephalic bleeding randomly will done under sterile condition at 26th day of LMP for them. After one month from intervention; time of menstruation is evaluated. Also insulin resistance and quality of life is evaluated before and two weeks after intervention. The participants in this study are 20-40 years old satisfied women with 60 days menstruation cycle and clinical hyper androgens that not be pregnant or lactating; don't have primary ovarian insufficient, thyroid dysfunction, diabetes mellitus, anemia, coagulation diseases, hyper prolactinemia and not users of hormonal or herbal drugs that effect on menstruation. The intervention is calves wet-cupping in control group and 20cc bleeding in witness group. The main outcome is decrease of menstruation period and vaginal bleeding and FBS, insulin, quality of life changes.

General information

Acronym

Poly Cystic Ovarian Syndrome

IRCT registration information

IRCT registration number: **IRCT2016080228664N2**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

Name

Azam Meyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0572

Email address

ameyari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Hamedan university of medical sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of wet cupping and blood donation on decrease of menstruation period and insulin resistance in polycystic ovarian syndrome (PCOS)

Public title

The effect of wet cupping on regulation of vaginal bleeding in Pcos

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: "20-40 years old women with minimum 60 days menstruation retardation (from LMP)" "Hirsutism according to ferriman Gallwey chart" "Not metformin or hormonal drugs users" "Personal satisfaction" Exit criteria: "Use of hormonal or herbal drugs that affect menstruation" "Positive BhcG" "Lactation" "Plan to pregnancy about 3 next months" "History of thyroid dysfunction" "History of anemia" "History of coagulation diseases" "History of diabetes mellitus" "FSH >40" "Hyperprolactinemia"

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Ave, Hamedan, Iran

City

Hamedan

Postal code

6517838678

Approval date

2016-06-11, 1395/03/22

Ethics committee reference number

IR.UMSHA.REC.1395.125

Health conditions studied

1

Description of health condition studied

Pcos

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Decrease of waste hairs growth

Timepoint

Before, 2,6 weeks after intervention

Method of measurement

Ask the patient and complete tracking form

2

Description

Decrease of menstruation cycle period

Timepoint

Before,2,6 weeks after intervention

Method of measurement

Ask the patient and complete tracking form

Secondary outcomes

1

Description

Decrease of insulin resistance

Timepoint

Before and 2 weeks after intervention

Method of measurement

Fasting blood suger & insulin assay

2

Description

Quality of life

Timepoint

Before and 4 weeks after intervention

Method of measurement

Ask the patient and complete tracking form

Intervention groups

1

Description

Calves wet-cupping will done at the 26th day of menstruation cycle in intervention group. When the patient is in the prone position, calf muscle is suctioned repeatedly to provide a negative pressure. Then under aseptic condition shallow incisions are made by a surgical blade parallel to the body plans and bleeding from incisions will be collected inside the cup through three times suction. Then skin will be cleaned and

covered by dressing. Vein bleeding will done in control group at 26th day from LMP. Intervention will done only once.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endometrium and Endometriosis Research Center

Full name of responsible person

Azam Meyari, Ph.D student of Traditional Medicine

Street address

Endometrium and Endometriosis Research Center,
Fatemieh Hospital, Pasdaran Ave, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and thecnology of
Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Vice chancellor for research and thecnology of
Hamedan University of Medical Sciences, Hamedan
University of Medical Sciences, Shahid Fahmideh Ave,
Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research and thecnology of Hamedan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Education and development of medical sciences
center, Hamedan University of Medical Sciences

Full name of responsible person

Azam Meyari

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

Street address

Education and development of medical sciences
center, Hamedan University of Medical Sciences,
Shahid Fahmideh Ave, Hamedan

City

Hamedan

Postal code

6517838736

Phone

+98 81 3838 0238

Fax

+98 81 3838 0246

Email

"d_a_meyari@yahoo.com" "ameyari@sbmu.ac.ir"

Web page address

dme.umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endometrium and endometriosis research center

Full name of responsible person

Dr. Mahnaz Yavangi

Position

Gynecologist, Associate Professor

Other areas of specialty/work

Street address

Endometrium and endometriosis research center,
Fatemieh Hospital, Pasdaran Ave, Hamedan

City

Hamedan

Postal code

6517789971

Phone

+98 81 3825 5474

Fax

+98 81 3828 3939

Email

yavangi@umsha.ac.ir

Web page address

eerc.umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Education and development of medical sciences,
Hamedan University of medical sciences

Full name of responsible person

Azam Meyari

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

Street address

Education and development of medical sciences,
Hamedan University of medical sciences, Shahid
Fahmideh Ave, Hamedan

City

Hamedan

Postal code

6517838736

Phone

+98 81 3838 0238

Fax

+98 81 3838 0246

Email**Web page address**

dme.umsha.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty