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

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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 suctions. 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

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

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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

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

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Person responsible for scientific inquiries

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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