

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the efficacy of calves wet cupping on vaginal bleeding induce in women with amenorrhea and oligomenorrhea.

Protocol summary

Summary

Objects: The aim of this study is to evaluate the effects of calves wet-cupping on menstruation in amenorrheic and oligomenorrheic women. Design: This study is before and after clinical trial with historical controls and is a single center trial. Study participants are 20 to 40 years old women with amenorrhea or oligomenorrhea that their average menstrual cycle has been 60 days long during past year. Sample size consists of 75 members and calves wet-cupping will be done under sterile condition at 26th day of LMP for all of them. After intervention, time, duration and number of menstruation cycles are evaluated. Also insulin resistance and hormonal changes are evaluated before and three months after intervention. The participants in this study are 20-40 years old women with 60 days menstruation cycle that aren't pregnant or lactating; don't have primary ovarian insufficiency, thyroid dysfunction, diabetes mellitus, anemia, coagulation diseases, hyperprolactinemia and not users of hormonal or herbal drugs that affect menstruation. The intervention is calves wet-cupping and its outcomes are vaginal bleeding and FBS, insulin, testosterone and SHBG changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062728664N1**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-04, 1395/05/14

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, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of calves wet cupping on vaginal bleeding induce in women with amenorrhea and oligomenorrhea.

Public title

The effect of wet-cupping on amenorrhea and oligomenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-40 years old women with minimum 60 days menstruation retardation (from LMP); personal satisfaction; Not metformin or hormonal drugs users.

Exclusion criteria: Use of hormonal or herbal drugs that

affect menstruation; Positive BhCG; Lactation; Plannig to be pregnant during the next 3 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: **75**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Postal code

198396-3113

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.SBMU.RAM.REC.1395.34

Health conditions studied

1

Description of health condition studied

Pcos

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2

Description of health condition studied

Ovarian dysfunction

ICD-10 code

E28.9

ICD-10 code description

Ovarian dysfunction, unspecified

Primary outcomes

1

Description

Menstrual blood volume

Timepoint

Before intervention and 1, 2, 4 and 12 weeks after intervention

Method of measurement

Ask the patient and complete tracking form

2

Description

Occurance of Menstrual bleeding

Timepoint

Before intervention and 1, 2, 4 and 12 weeks after intervention

Method of measurement

Ask the patient

3

Description

Duration of menstural bleeding

Timepoint

Before intervention and 1, 2, 4 and 12 weeks after intervention

Method of measurement

Ask the patient and complete tracking form

Secondary outcomes

1

Description

SHBG

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

SHBG serum assay

2

Description

Testosterone

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Serum testosterone assay

3

Description

Insulin resistance

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Fasting blood sugar & insulin assay

4

Description

Quality of life

Timepoint

Before intervention and 4&12 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. 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. Intervention will done only once.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Fatemieh hospital

Full name of responsible person

Azam Meyari

Street address

Pasdaran ave, Hamedan, Iran

City

Hamedan

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

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 of Shahid Beheshti 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**

Traditional school of Shahid Beheshti 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**

No.8, Shams Alley, opposite Tavanir, Vali Asr Street, Tehran, Iran

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Traditional Medicine of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mojgan Tansaz

Position

Traditional medicine specialist, Assistant Professor

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Person responsible for updating data

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Full name of responsible person

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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