Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Effect Of Leech therapy and Dry cupping with Contraceptives LD on Improvement of Menstrual Complaints in Women with Polycystic Ovary Syndrome

Protocol summary

Study aim

Determining the effect of Leech Therapy And Dry Cupping With Contraceptives LD On Improvement Of Menstrual Complaints In Women With Polycystic Ovary Syndrome

Design

Clinical trial with control group, Blinded, Randomised, with 40 Patients

Settings and conduct

The present study will be performed on women aged 18 to 40 who refer to Gonabad and Bojnourd traditional medicine centers. 40 patients, If they have arrival conditions, are randomly divided into two groups. In one group, Leech therapy and dry cupping will be done.This will be done once a week after the menstrual bleeding until the next menstrual period.The second group consume Low dose (LD) tablets by starting menstruation on daily basis for 21 days.These interventions will be performed in two months, and the duration of menstrual cycle, bleeding volume and menstrual pain will be followed up monthly by their special questionnaire for three months. Also the present study of a one-way is blind and the study for a person who is responsible for statistical analysis will be blind and does not know which questionnaire is related to which intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria:Women 18 to 40 years of age have polycystic ovaries, Body mass index Between 18.5 to 24.9 Exclusion criteria: Individual Intolerance to Leeches or Cupping or LD, Unwillingness to Continue Participate in the Study

Intervention groups

Intervention group: Intervention with leech therapy and Dry cupping will be Performed once a week after the end of menstrual bleeding until the next menstrual period control group: LD contraceptive pills should be taken daily for 21 days from the beginning of menstruation, and then the pill should be stopped for 7 days and another pack should be started Interventions will be done for 2 months

Main outcome variables

Duration of the menstrual cycle, Menstrual bleeding volume, Menstrual cramps

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047903N1**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Ainaz Khodaverdian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 3280

Email address

ainazkvn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-25, 1399/05/04

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Leech therapy and Dry cupping with Contraceptives LD on Improvement of Menstrual Complaints in Women with Polycystic Ovary Syndrome

Public title

Effect of Leech Therapy and Dry cupping on Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Polycystic Ovaries based on the individual's satatement Having Written and oral consent to participate in the study Age range of 18 to 40 Having reading and writing Literacy Body mass index Between 18.5 to 24.9 Lack of drug use No having chronic physical disease They did not Receive any Treatment for Polycystic Ovaries for 6 Months ago Failing to use hormonal drugs during the study Do not Take Hormonal Medications During the Study Patients with Stable Medical Condition Not Pregnant No Breastfeeding People with Oligomenorrhea

Exclusion criteria:

Individual Intolerance to Leeches or Dry Cupping or LD

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For sampling, first each qualified person is selected to enter the study and Then the samples will be placed in the available method based on 4 blocks and random allocation in each of the two intervention groups (intervention) A or (control) B. 4 blocks will be used for sampling(AABB, ABAB, BBAA, BABA, ABBA,BAAB)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study each questionnaire will be marked with the letters A (intervention group) and B (control group). People who do statistical work and analysis of data are blind to each participant than the intervention provided in this way, the person does not know which questionnaire is related to which intervention.After explaining the research to the research units and obtaining informed written consent based on random allocation, they will be placed in two groups of intervention and control 4 blocks will be used for sampling(AABB, ABAB, BBAA, BABA, ABBA,BAAB)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

No. 79, Ranjbar Ave., West Taleghani

City

Bojnourd

Province

North Khorasan

Postal code

9414844364

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

1399.033.IR.GMU.REC.

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

The Duration of the Menstrual cycle

Timepoint

Before the Intervention, 1 Month, 2 and 3 Months after the Intervention

Method of measurement

A Researcher-made Questionnaire and Calendar

2

Description

Menstrual Bleeding Volume

Timepoint

Before the Intervention, 1 Month, 2 and 3 Months after the Intervention

Method of measurement

Blood Visual Assessment Questionnaire

3

Description

The Severity of Menstrual Cramps

Timepoint

Before the Intervention, 1 Month, 2 and 3 Months after the Intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Satisfaction with Treatment

Timepoint

After the Intervention

Method of measurement

Questionnaire

2

Description

Complications

Timepoint

After the Intervention

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: In this group, Leech therapy and Dry cupping will be Performed once a week after the end of Menstrual Bleeding until the Start of the next Menstrual Period. At first Place Leeches from the Farthest Point to the Uterus,That is on the Ankle and then on the Waist an Uterus. Dry cupping with Leech Therapy will be Placed around the Navel and in the Back (around the Spine).This will be done for two months and people are followed up for 3 months

Category

Treatment - Other

2

Description

Control group: This group is treated with Low dose (LD) pills with a combination of 0.03 mg of Ethinyl Estradiol and 0.15 mg of Levonorgestrel.It should be taken daily and at a specific time by the Person for 21 days from the Beginning of Menstruation and then the pill should be Stopped for 7 day and another pack should be started again.This will continue for two Consecutive Cycles

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bojnourd and Gonabad Traditional medicine centers

Full name of responsible person

Ainaz Khodaverdian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

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9691793718

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khosravan@gmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Ainaz Khodaverdian
Position
Masters Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available