Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Evaluating the effect of dry cupping, and Aslaq capsule, on the incidence of pregnancy in patients with infertility due to polycystic ovary syndrome

Protocol summary

Study aim
Comparison of the effect of cupping, aslaq capsule, aslaq capsule with cupping, and letrozole on pregnancy rate in patients with infertility due to polycystic ovary syndrome

Design
Clinical trial with control group, with parallel groups, randomized, phase 3, on 120 patients. Statistical software R version 4.0.2 was used for randomization.

Settings and conduct
Location: Molud Infertility Center of Zahedan - In the Letrozole group, 5 mg per day, 3th to 7th of menstruation - In the cupping + letrozole group: cupping daily for 15 to 20 min from the 7th to the 14th days of mensuration + letrozole - In the aslaq capsule + Letrozole group: 2 aslaq capsules a day for 21 days from the first day of cleansing, then the capsule is stopped until menstruation occurs + Letrozole - In the cupping + aslaq capsule + Letrozole group: combination of aslaq capsule+cupping is considered+ Letrozole. For all patients on day 13 of the menstrual cycle, ultrasound is performed for following the growth of ovarian follicles. Each patient will be in the study for a maximum of 6months, unless no improvement in the parameters is seen after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: PCOs based on Rotterdam criteria and diagnosing infertility fellowship, Infertility with at least one year of unprotected intercourse, Age between 18 and 35 years Exclusion criteria: Systemic disease requires serious therapeutic interventions, premature ovarian failure, Single ovarian cyst or breast cyst Endometriosis, Pelvic Adhesions, Tube Obstruction, Tube Abnormalities, and Hyperprolactinemia, Infertility due to male factor

Intervention groups
Patients are randomly assigned to one of the following four groups: Group 1: Aslaq capsule (Touba company) + cupping + Letrozole Group 2: Aslaq capsules + Letrozole Group 3: cupping + Letrozole Group 4: Letrozole

Main outcome variables
Occurrence of pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180923041093N7**
Registration date: **2022-07-04, 1401/04/13**
Registration timing: **prospective**

Last update: **2022-07-04, 1401/04/13**
Update count: **0**

Registration date
2022-07-04, 1401/04/13

Registrant information

Name
Fatemeh sadat Hasheminasab

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-21, 1401/04/30

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of dry cupping, and Aslaq capsule, on the incidence of pregnancy in patients with infertility due to polycystic ovary syndrome

Public title
Evaluating the effect of dry cupping, and Aslaq capsule, on the infertility

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
PCOs based on Rotterdam criteria and diagnosing infertility fellowship Infertility with at least one year of unprotected intercourse Age between 18 and 35 years

Exclusion criteria:
Systemic disease requires serious therapeutic interventions premature ovarian failure Single ovarian cyst or breast cyst Endometriosis, Pelvic Adhesions, Tube Obstruction, Tube Abnormalities, and Hyperprolactinemia Infertility due to male factor

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: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of patients to four groups is done by permuted block stratified randomization. In this way, eligible patients are first classified according to BMI, consumption or non-consumption of metformin, and regular or irregular menstruation (oligomenorrhea or amenorrhea), respectively. Then, based on the four blocks (consisting of four groups A, B, C and D) that are randomly selected from all possible modes of permutations, they are assigned to the desired group. These blocks are created using R statistical software version 4.0.2.

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
Research Ethics Committees of Zahedan University Of Medical Sciences

Street address
Dr. Hesabi Square, Persian Gulf Boulevard -

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Sistan-va-Balouchestan

Postal code
98167-43463

Approval date
2022-04-17, 1401/01/28

Ethics committee reference number
IR.ZAUMS.REC.1401.105

Health conditions studied

1

Description of health condition studied
Infertility due to polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
time of pregnancy occurrence

Timepoint
After the intervention

Method of measurement
sonography or BHCG

Secondary outcomes

1

Description
Menstrual pain

Timepoint
Monthly

Method of measurement
Visual analogue scale

2

Description
The length of the menstrual cycle

Timepoint
Monthly

Method of measurement

Time interval from the first day of menstrual bleeding to the last day of menstrual bleeding in a cycle. Based on the person's response to the questionnaire

3

Description
Ovulation rate
Timepoint
Monthly
Method of measurement
Ultrasonography

4

Description
Endometrial thickness
Timepoint
Monthly - Day 13 of the menstrual cycle
Method of measurement
Ultrasonography

5

Description
Follicle growth
Timepoint
Monthly - Day 13 of the menstrual cycle
Method of measurement
Ultrasonography

6

Description
Sexual function
Timepoint
At the beginning of the intervention, three and six months after the start of the intervention
Method of measurement
Female sexual function index

Intervention groups

1

Description
Intervention group: cupping+ Letrozole- 2.5 mg letrozole tablets twice a day, on days 3 to 7 of menstruation. Moreover, from the seventh day of the menstrual cycle to the fourteenth day, dry cupping under the abdomen (the area between the upper area of the symphysis pubis bone - above the pubic hairline - and below the navel) will be done using four cups with a diameter of 6 cm. Patients are trained for cupping. In this way, castor oil is applied to the lower abdomen and 4 cups are placed on it, then a vacuum is created by the suction device that is provided to the patients so that the skin protrudes in the glass and becomes slightly red due to the accumulation of blood. The cups are left for 15 to 20 minutes and then gently removed. In the grouping group, if menstruation does not occur on day 35 of the cycle, the beta test is taken from the patient, and if the test is negative, cupping is performed again for 5 days, and if menstruation occurs, the stopping is stopped. If menstruation does not occur with cupping, the patient will be excluded from the study for other treatments.
Category
Treatment - Drugs

2

Description
Intervention group: Aslaq capsule+ Letrozole- 2.5 mg letrozole tablets twice a day, on days 3 to 7 of menstruation. Moreover, from the first day of cleansing for 21 days, one Asalq capsule in the morning, one capsule at night, then the capsule is cut until menstruation occurs and the next cycle of taking the capsule starts from the first day of cleansing the next cycle. If no menstruation occurs 6 days after discontinuation of the capsule, the beta test is taken from the patient and if the test is negative, the seventh day (seven days after discontinuation of the capsule) the capsule is started again. If menstruation does not occur after two periods of taking the capsule, the patient will be excluded from the study for other treatments.
Category
Treatment - Drugs

3

Description
Intervention group: Aslaq capsule and cupping+ Letrozole- 2.5 mg letrozole tablets twice a day, on days 3 to 7 of menstruation. Moreover, a combination of Aslaq capsule and cupping is used. The cupping from day 7 to 14 of the menstrual cycle and the capsule are considered for 21 days from the first day of cleansing. In case of no menstruation 6 days after discontinuation of the capsule, the beta test is taken from the patient and if the test is negative, on the seventh day (seven days after discontinuation of the capsule) the capsule is started again and at the same time with the start of the capsule, the cupping is done for 5 days. At this stage, if menstruation occurs, the cupping and the capsule are cut off. If menstruation does not occur after two periods of taking the capsule with the cupping, the patient will be excluded from the study to receive other treatments.
Category
Treatment - Drugs

4

Description
Control group: letrozole - 2.5 mg tablets twice a day, 5 days in a cycle will start from the third day of menstruation. If you do not menstruate after 50 days from the start of the previous cycle, 200 mg of progesterone is prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Molud infertility center in Ali Ibn Abi Talib Hospital, Zahedan

Full name of responsible person
Marziye Ghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Fatemeh Sadat Hasheminasab

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Pharmacology research center, Zahedan university of medical sciences, Hesabi square, Zahedan, Iran

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Person responsible for updating data

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Ph.D.

Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the study, information about the main outcome will be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

For academic and scientific researchers only

Under which criteria data/document could be used

Only in line with the analysis and research related to the main title of this study

From where data/document is obtainable

Email to hashemifa67@gmail.com

What processes are involved for a request to access data/document

The data will be provided to the applicant within one month after reviewing and confirming the request.

Comments