Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Traditional Iranian Medicine product (based on Celery and Anise seed) with metformin on oligomenorrhea in patients with polycystic ovary syndrome(PCOs)

Protocol summary

Summary

This study is a triple-blind randomized clinical trial that will examin the effect of traditional medicine products based on celery and anise on oligomenorrhea treatment of patients with polycystic ovary syndrome and the effect of metformin in the treatment of these patients in comparison. 72 patients 18 to 40 years old with PCOs who will refer with oligomenorrhea complaint to the outpatient clinic of the academic center after confirming gynecologist and qualifying criteria, including the absence of other systemic diseases (such as diabetes, hyperprolactinemia, thyroid disorders Chronic liver, kidney, diseases and epilepsy) and lack of pregnancy and lactation will be in the study. The subjects were randomly divided into two groups of 36 persons (receiver anise and celery products and metformin). For all patients at the baseline, ultrasound of the uterus, ovaries and hormonal and biochemical diagnostic tests will be done. In the group receiving traditional medicine products,they will use 4.5 g celery and anise powder(6capsules divided into 3 meals) for two weeks. If the menstruation occurs at each stage of using the drug,the herbal drug will cut and one placebo capsule will be used after every meal. After purity, restart the herbal medication and this process is repeated 3 cycles. In the absence of menstrual like mensturation days herbal drug will cut and one placebo capsule will be used after every meal for two weeks. After four weeks of therapy(two-week using of herbal drug and waiting two weeks and using placebo),if the mensturation does not occur, re-start taking the herbal product. This process is repeated three times. In the group taking metformin,1500 mg metformin powder(6 capsules divided into 3 meals) for two weeks . In the menstruation days and the menstruation waited days,one metformin powder(500mg) capsule will be used. The main out come of this study is occurance of menstural bleeding, the duration of bleeding, menstrual bleeding volume, menstrual cycle length and duration of treatment until the occurrence of bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092413566N6**
Registration date: **2016-01-13, 1394/10/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-13, 1394/10/23

Registrant information

Name

Kobra Hamdi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology Tabriz University of Medical Sciences-Dr. Mohammad Rashidi.Tabriz-Gogasht street, Tabriz University of Medical Sciences-Central Building number 2-third floor-Deputy of research and technology.East Azarbaijan-Iran.phone number: 0098413335731- fax number:00984133344280 .www.tbzmed.ac.ir/Research-rashidi@tbzmed.ac.ir

Expected recruitment start date
2016-01-05, 1394/10/15
Expected recruitment end date
2016-09-05, 1395/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Traditional Iranian Medicine product (based on Celery and Anise seed) with metformin on oligomenorrhea in patients with polycystic ovary syndrome(PCOs)

Public title
Effect of Celery and Anise on oligomenorrhea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients satisfaction , Patients with PCOS that their main complaint is oligomenorrhea, age 40-18 years, no pregnancy, no abortion or within 6 weeks post partum; lack of breastfeeding, absence of any systemic diseases such as hyperinsulinemia and hyperandrogenism, diabetes, Cushing's syndrome, congenital adrenal hyperplasia, hyperprolactinemia, thyroid disorders, body mass index between 18 and 35 kg / m2; non-hormonal drugs in the last month, lack of uterine malignancies, ovarian and other malignancies;lack of Chronic liver disease and kidney failure, lack of headaches and epilepsy; willingness to participate in the study. Exclusion criteria: use of hormonal drugs during the study, the incidence of side effects, the need for other interventions and surgery, pregnancy during the study, patient request for exclusion.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences- Deputy of research and technology-Ethic committee
Street address
Tabriz-Gogasht street, Tabriz University of Medical Sciences-Central Building number 2-third floor-Deputy of research and technology
City
Tabriz
Postal code
Approval date
2015-09-14, 1394/06/23
Ethics committee reference number
TBZMED.REC.1394.530

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Experience of menstural bleeding
Timepoint
Before intervention and 1,2, 3, 4 month after intervention
Method of measurement
Ask the patient and complete tracking form

Secondary outcomes

1

Description
Duration of bleeding
Timepoint
Before intervention and 1,2,3, 4 month after intervention
Method of measurement
Ask the patient and complete tracking form

2

Description
Menstrual blood volume

Timepoint
Before intervention and1,2, 3, 4 month after intervention
Method of measurement
Pictorial Blood Loss Assessment Chart (PBAC)

3

Description
Menstrual cycle length
Timepoint
Before intervention and1,2, 3, 4 month after intervention
Method of measurement
Ask the patient and complete tracking form

4

Description
serum LH
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Serum analysis by ELIZA

5

Description
LH/FSH proportion
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Serum analysis by ELIZA

6

Description
Free Testosterone
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Serum analysis by ELIZA

7

Description
Fasting Blood Suger(FBS)
Timepoint
Before intervention and 3 month after intervention
Method of measurement
blood biochemistrical analysis

8

Description
Liver function test(AST,ALT)
Timepoint
Before intervention and 3 month after intervention
Method of measurement
spectophotometry

Intervention groups

1

Description
Intervention group:In the group receiving traditional medicine products,patient will use 4.5 g celery and anise powder (6 capsules divided into 3 meals) for two weeks. If the menstruation occurs at each stage of using the drug, the herbal drug will cut and one placebo capsule will be used after every meal. After purity, restart the herbal medication and this process is repeated 3 cycles.
Category
Treatment - Drugs

2

Description
Control group:In the group taking metformin,1500 mg metformin powder(6 capsules divided into 3 meals) for two weeks . In the menstruation days and the menstruation waited days,one metformin powder(500mg) capsule will be used.After purity,1500 mg metformin powder(6 capsules divided into 3 meals)repeatedly will be prescribed and this process is repeated 3 cycles.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital affiliated withTabriz University of Medical Sciences
Full name of responsible person
Arezoo Moini Jazani
Street address
Tabriz- South Army street-Baghshomal crossroad-Al-Zahra hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences-Deputy of Research and Technolog
Full name of responsible person
Dr.Mohammad Reza Rashidi
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Tabriz-Gogasht street, Tabriz University of Medical Sciences-Central Building number 2-third floor-Deputy of research and technolog
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences-Deputy of Research and Technolog
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
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Position
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Person responsible for updating data

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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