Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of “ma_ol_asal” syrup on the treatment of Polycystic Ovarian Syndrome

Protocol summary

Study aim
The use of “ma_ol_asal” syrup in the treatment of patients with polycystic ovary syndrome

Design
Clinical trial without control group on 20 patients to evaluate the effectiveness of “ma_ol_asal” syrup in the treatment of patients with polycystic ovary syndrome

Settings and conduct
The present study is an experimental clinical trial in which the effect of “ma_ol_asal” syrup product on menstrual bleeding in women with PCOS with oligomenorrhea complaint referred to the gynecological clinic of Touba Clinic in Sari is investigated. Among those referred to the clinic, married and single women with PCOS aged 18-40 years with an oligomenorrhea complaint who meet the inclusion criteria are considered as the target population.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All women with polycystic ovary syndrome present with oligomenorrhea and are satisfied with the study. exclusion criteria: 1. People with any type of systemic disease such as diabetes, Cushing's, adrenal hyperplasia, hyperthyroidism 2. Pregnant women and women who are breastfeeding either intend to become pregnant or women who have had an abortion 3. People taking hormonal drugs, including LD pills 4. People with a history of breast and ovarian cancer and people undergoing chemotherapy

Intervention groups
At the beginning of the study, after taking the history and clinical examinations and determining the mood by the relevant questionnaire, patients enter the plan. How to take the drug: three times a day, each meal 10 cc after each meal. In the second week, the necessary follow-up is done by the researcher. The duration of the intervention will be three months, during which the patient will be monitored by a doctor.

Main outcome variables
The effect of “ma_ol_asal” syrup on the duration of bleeding, body mass index in patients with polycystic ovary syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200112046087N5**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date
2020-11-22, 1399/09/02

Registrant information

Name
Hanieh Babaei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8877 3521

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haniehbabaei92@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of “ma_ol_asal” syrup on the treatment of Polycystic Ovarian Syndrome

Public title
The effect of compound “ma_ol_asal” syrup on oligomenorrhea in patients with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All women with PCO who present with an oligomenorrhea complaint and consent to the study

Exclusion criteria:
People with any type of systemic disease such as diabetes, Cushing's, adrenal hyperplasia, hyperprolactin, hyper thyroidism Pregnant women and women who are breastfeeding (the first 6 months) are either planning to become pregnant or women who have had an abortion People taking hormonal medications, including LD pills People with a history of breast and ovarian cancer and people undergoing chemotherapy

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

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

Approval date
empty

Ethics committee reference number

2

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical sciences, Daneshju Blv.

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2020-10-12, 1399/07/21

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.597

Health conditions studied

1

Description of health condition studied
Oligomenorrhoea

ICD-10 code
N91.4

ICD-10 code description
Secondary Oligomenorrhoea

Primary outcomes

1

Description
The effect of “ma_ol_asal”syrup on the duration of bleeding in patients with polycystic ovary syndrome

Timepoint
Before entering the study and after the treatment period

Method of measurement
Question from the patient

2

Description
The effect of “ma_ol_asal” syrup on bleeding rate in patients with polycystic ovary syndrome

Timepoint
Before entering the study and after the treatment period

Method of measurement
Pictorial Bleeding Assessment Chart (PBAC)

3

Description
The effect of “ma_ol_asal” syrup on BMI in patients with polycystic ovary syndrome

Timepoint
Before entering the study and after the treatment period

Method of measurement
Meters and scales and BMI formula

Secondary outcomes

1

Description
Menstrual period
Timepoint
Before entering the study and after the treatment period
Method of measurement
Question from the patient

2

Description
Cleanliness period
Timepoint
Before entering the study and after the treatment period
Method of measurement
Question from the patient

Intervention groups

1

Description
Category
empty

2

Description
Intervention group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Touba Clinic
Full name of responsible person
marziehzamaniyan
Street address
Mazandaran province, Sari city, Khazar boulevard, former medical school, Toobi specialized and sub-specialized clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Traditional Medicine and Materia Medica Research Center
Full name of responsible person
Rasool Choopani Zanjani
Street address
No. 8, Shams Alley, Vali-e Asr Ave, The Faculty of Traditional Medicine of Shahid Beheshti University of Medical Sciences
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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
Traditional Medicine and Materia Medica Research Center
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
Shahid Beheshti School of Traditional Medicine
Full name of responsible person
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the studied items such as BMI, bleeding volume, menstrual period, etc. will be provided to the researchers.
When the data will become available and for how long
Start the access period at least one month after the results are published
To whom data/document is available
researchers
Under which criteria data/document could be used
After the publication of the article extracted from the clinical trial, the said person will notify his / her request by email or contact.
From where data/document is obtainable
Executor of the project, Ms. Dr. Mojgan Tanzaz tansaz_mojgan@yahoo.com Tel: 02188773525
What processes are involved for a request to access data/document
After sending an email to Dr. Tan Saz, at his discretion and with the approval of the Vice Chancellor for Research, Shahid Beheshti School of Traditional Medicine, the required information will be provided.
Comments