

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

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

City

Sari

Province

Mazandaran

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4815733971

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marziehzamaniyan@gmail.com

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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1516745811

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Email

itmrc@sbm.ac.ir

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

Hanieh Babaei

Position

reasercher

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Faculty of Traditional Medicine, Shahid Beheshti University

Full name of responsible person

Mojgan Tansaz

Position

Assistant Professor, Faculty of Traditional Medicine, Shahid Beheshti University

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

Master

Other areas of specialty/work

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haniehbabaei92@gmail.com

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 Tansaz
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