Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of effect of wild mint product on oligo/Amenorrhea by Viewpoints of traditional Iranian medicine

Protocol summary

Summary

This is a double-blind, placebo-controlled, multicentral randomized clinical trial to asses the effects of herbal products of wild mint on the women with olig/Aomenorrhea according to the Iranian traditional medicine view point. In this study, 120 patients are accepted based on inclusion criteria. Age range in our sample is between 18 to 35 years. Patients' hormones (TSH, FSH, PRL) would not be higher than normal. They would not be pregnant and breastfeeding. When we select our samples, we randomly divide them to two groups. We use the coded drugs with same shape without name. The dose of drug is 15ml, which is administered in three times in a day for two weeks. If the patients do not menstruate after 2 weeks of taking the drug, we will wait for two more weeks again. After four weeks of therapy if the patients still do not menstruate, we will use the drugs for two more weeks . If the patients menstruate at each stage of using the drug, we start it one week after the end of menstruation. But if the patients were not menstruate after four weeks (two-week using of drug and waiting two weeks), we repeat the previous steps. The drug and placebo is repeated three cycles. At the baseline of the study, ovaries and uterus ultra sonography, blood cell count (CBC), hormonal tests including17OH, TSH, LH, FSH, PRL, total Testosterone and free Testosterone are done. At the end of the study, all patients are visited again and important data are collected through interviews and questionnaires. Also hormone levels (LH, FSH, Total Testosterone, free Testosterone) and CBC are repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110027690N1**
Registration date: **2011-12-09, 1390/09/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-12-09, 1390/09/18

Registrant information

Name
Roshanak Mokaberinejad
Name of organization / entity
Shahed university
Country
Iran (Islamic Republic of)
Phone
+98 21 2296 3533
Email address
mokaberi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of wild mint product on oligo/Amenorrhea by Viewpoints of traditional Iranian medicine

Public title

Effect of wild mint on oligomenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patient satisfaction; Outpatients aged between18-35 years; More than two months of oligomenorrhea; Negative pregnancy test; Not breastfeeding; Patient's hormones (TSH, FSH, PRL) not higher than normal; No Hormonal treatment (chemical or plant) is allowed at the same time; No malignancies; No chronic kidney disease and liver disease; Stress is not one of the reason for delayed menstruation. Exclusion criteria: Patients that use hormone therapy; Patients who experienced side effects; Patients who need surgery and other interventions; Patients with a personal decision to exit from the study.
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
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahed university
Street address
Qom-Tehran Highway
City
Tehran
Postal code
1415635111
Approval date
2011-05-31, 1390/03/10
Ethics committee reference number
4/112251

Health conditions studied

1

Description of health condition studied
Oligomenorrhea
ICD-10 code
N91.4
ICD-10 code description
Secondary oligomenorrhoea

Primary outcomes

1

Description
Start of bleeding
Timepoint
Before intervention and 1, 2 & 3 months later
Method of measurement
Question

2

Description
FSH
Timepoint
Beginning & end of study
Method of measurement
ELISA

3

Description
LH
Timepoint
Beginning & end of study
Method of measurement
ELISA

4

Description
testosterone
Timepoint
Beginning & end of study
Method of measurement
ELISA

5

Description
free testosterone
Timepoint
Beginning & end of study
Method of measurement
ELISA

Secondary outcomes

1

Description
Side effects
Timepoint

During the study

Method of measurement

Question

Intervention groups

1

Description

Syrup of wild mint, 3 times each day, each time 15 cc, 3 cycles of menstruation

Category

Treatment - Drugs

2

Description

Syrup of glucose, 3 times each day, each time 15cc, 3 cycles of menstruation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Dr. Roshanak Mokaberinejad

Street address

Italia avenue

City

Tehran

2

Recruitment center

Name of recruitment center

Dormitory of Shahed University

Full name of responsible person

Dr. Roshanak Mokaberinejad

Street address

Zamani alley, Nejatollahi st.

City

Tehran

3

Recruitment center

Name of recruitment center

Added at June 4, 2012: Emam Khomeini Hospital

Full name of responsible person

Roshanak Mokaberinejad

Street address

Touhid Squre

City

Tehran

4

Recruitment center

Name of recruitment center

Added at 2012-08-28: Private clinic of Mrs. Soodabe Bioos

Full name of responsible person

Added at 2012-08-28: Dr.Roshanak Mokaberinejad

Street address

Added at 2012-08-28: Charmardan Street

City

Added at 2012-08-28: Qom

5

Recruitment center

Name of recruitment center

Added at 2012-08-28: Hazrat zeinab Hospital

Full name of responsible person

Added at 2012-08-28: Dr Roshanak Mokaberinejad

Street address

Added at 2012-08-28: Forsat Ave, Taleghani St

City

Added at 2012-08-28: Tehran

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Recruitment center

Name of recruitment center

Added at 2012-08-28: Salamat clinic

Full name of responsible person

Added at 2012-08-28: Dr. Roshanak Mokaberinejad

Street address

Added at 2012-08-28: Third.Dashtestan, Sharieati Ave

City

Added at 2012-08-28: Tehran

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Recruitment center

Name of recruitment center

Added at 2012-08-28: Khark clinic

Full name of responsible person

Added at 2012-08-28: Dr Roshanak Mokaberinejad

Street address

Added at 2012-08-28: Khark Ave, Enghelab St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Mohsen Naseri

Street address

Qom-Tehran highway

City

Tehran

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
Roshanak Mokaberinejad
Position
PhD student in traditional medicine
Other areas of specialty/work
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Person responsible for scientific inquiries

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Gynecologist & faculty member
Other areas of specialty/work
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Fax
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nafise_zafar@yahoo.com
Web page address

Person responsible for updating data

Contact

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