

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of Sesamum indicum L. and medroxyprogesteron on oligomenorrhea: a Single blind randomized clinical trial

Protocol summary

Summary

This is a Single blind randomized clinical trial that will be done on females of 20-40 y/o admitting clinics with chief complaint of oligomenorrhea. The Study goal is to compare the effect of Sesamum indicum L. and medroxyprogesteron on oligomenorrhea. The Inclusion criteria are: 20-40 y/o women with cessation of menstrual bleeding for more than 14 days that has been repeated for at least 3 episodes during the last year and are not pregnant or lactating. The exclusion criteria are: using hormonal drugs during the study or those who decide to exit the study. The overall sample size is 50, which will be divided in to the herbal drug (25 patients) and the control group (25 patients). After prescribing the herbal drug (Sesamum 60 grams daily) or the standard therapy (Medroxy Progesterone acetate 10 mgs daily) for one week, the patients will be followed for 2 and 4 weeks and will be asked for menstruation bleeding initiation, time to start the therapeutic effect, dysmenorrhea and possible treatment side effects. The response rate will be compared between the groups using t student test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072014072N1**

Registration date: **2013-12-21, 1392/09/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-21, 1392/09/30

Registrant information

Name

Maryam Yavari

Name of organization / entity

Shaheed Beheshty University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

mahnam@eng.ui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-12-11, 1392/09/20

Expected recruitment end date

2014-02-25, 1392/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Sesamum indicum L. and medroxyprogesteron on oligomenorrhea: a Single blind randomized clinical trial

Public title

Comparison of the effect of Sesamum indicum L. and medroxyprogesteron on menstrual bleeding cessation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-40 y/o women; willing to participate in the study; cessation of menstrual bleeding for more than 14 days that has been repeated for at least 3 episodes during the last year; negative pregnancy test; not in lactation period; not affected by: diabetes, hypertension, organic disease and malignancies, chronic

disease of the liver and kidneys; not using any kind of hormonal drugs(e.g. OCP) Exclusion criteria: Using hormonal drugs or any drug that will affect menstruation during the treatment period; patients willing to exit the study; patients that need invasive treatments during the study Exclusion criteria: Using hormonal drugs during the study experiencing drugs side effects patients who need interventions like surgery procedures those who will to exit the study

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshty University of Medical Sciences Eitic
Committee

Street address

Velenjak St., Shahid Chamran Highway

City

Tehran

Postal code**Approval date**

2013-12-01, 1392/09/10

Ethics committee reference number

143

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**

menstrual bleeding initiation

Timepoint

2 weeks and 4 weeks after finishing the drug
consumption

Method of measurement

interview

2**Description**

waiting period before menstrual bleeding

Timepoint

2 weeks after finish the drug consumption

Method of measurement

interview

Secondary outcomes**1****Description**

weight gain

Timepoint

during the study

Method of measurement

interview

2**Description**

hirsutism

Timepoint

during the study

Method of measurement

interview

3**Description**

Acne

Timepoint

during the study

Method of measurement

interview

4**Description**

nausia

Timepoint

during the study

Method of measurement

interview

Intervention groups

1

Description

Sesame seed product: 60 g daily for one week

Category

Treatment - Drugs

2

Description

Medroxyprogesterone acetate 5 mg tablets BID for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshty Hospital

Full name of responsible person

Dr Safoura Rouholamin

Street address

Motahari St., beside Felezi Brg.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Somaye Esmaeili

Street address

Shams alley, Tavanir St., Valiasr st.,

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshty University of Medical Sciences

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

Faculty of Traditional Medicine, Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Maryam Yavari

Position

PhD candidate

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Student

Other areas of specialty/work

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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