

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

#### Street address

Shams alley, Tavanir st., Valiasr st.

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yavari@med.mui.ac.ir

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshty University of Medical Sciences

#### Full name of responsible person

Dr Mojgan Tansaz

#### Position

MD, PhD in Traditional medicine

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Faculty of ztraditional Medicine, Shahid Beheshty University of Medical Sciences

#### Full name of responsible person

Maryam Yavari

#### Position

Student

#### Other areas of specialty/work

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#### Postal code

**Phone**  
+98 21 8877 3521  
**Fax**  
**Email**  
**Web page address**

## **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*