

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of traditional medicine product and medroxyprogesterone tablet on oligo/Amenorrhea in women of reproductive age

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

This study is a randomized clinical trial to compare the effectiveness of combined herbal product based on fennel with medroxyprogesterone tablet on women with oligo/Amenorrhea from the perspective of traditional persian medicine. 40 patients are accepted based on inclusion criteria. Age range in our sample is between 18 to 40 years. Then randomly divided into two groups intervention and control. In the case group is used of fennel combined product and in control group is used pills medroxyprogesterone 5 mg. The herbal product is used twice a day and the duration of the use is two weeks in each period, which begins in the second and third period after one week after menstruation. 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. medroxyprogesterone 5 Mg tablets are also used for 10 days (from 16 to 25 monthly cycles in later cycles) and twice a day. The minimum duration of treatment in this study, three months. At baseline for all patients, ultrasound of the ovaries and uterus, CBC, hormonal tests include: TSH, LH, FSH, PRL, Total Testosterone, for patients is requested. At the end of the study, all patients seen and the necessary data were collected through interviews and questionnaires, and all the tests are repeated.

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Farnoush Falahat

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2189

Email address

falahatf901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Center of Mashhad University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015063022987N1**

Registration date: **2017-11-19, 1396/08/28**

Scientific title

Comparison of traditional medicine product and medroxyprogesterone tablet on oligo/Amenorrhea in women of reproductive age

Public title

The effects of traditional medicine Product on oligomenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with oligo/Amenorrhea; Aged between 18 to 40 years; Negative pregnancy test; Patient satisfaction . Exclusion criteria: Pregnancy or breast-feeding; Abnormal prolactin levels ;Abnormal thyroid function tests ; FSH> 20 IU / L ;History of organic diseases or gynecological neoplasia;History of chronic renal or hepatic diseases; Severe drug allergy or a history of severe reactions toward unusual plants; Use of Ciprofloxacin, dopamine agonists and antagonists, anti androgens and estrogens; History of any type of chemical hormonal products in 1 month ago; Patients who need other interventions and surgery; Patients with a personal decision to exit from the study

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Sciences

Street address

University Avenue, Building Qureshi

City

Mashhad

Postal code**Approval date**

2015-05-14, 1394/02/24

Ethics committee reference number

IR.MUMS.REC.1394.67

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**

total 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

Medroxyprogesterone tablets 5 mg, twice a day, for 10 days and in subsequent cycles from 16 to 25 menstruation in the same way

Category

Treatment - Drugs

2

Description

Combined herbal tea based on fennel, 2 times a day, each time a t-bag, for 3 menstrual periods. Duration of use is two weeks in each course that begins a week after purity in period 2 and 3.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic for Persian Traditional Medicine, Imam Reza (AS) Hospital

Full name of responsible person

Farnoush Falahat

Street address

Special clinic for Persian Traditional Medicine, Imam Reza Sq, Ibn Sina St., Mashhad.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Cancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Cancellor for Research, Mashhad University of Medical Sciences, Daneshgah Ave., Golestan Crossroads

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Cancellor for Research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Farnoush Falahat

Position

PhD student of Persian and Complementary Medicine

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