

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Compare the effect of the drug agnogol and metformin on oligomenorrhea in patients with polycystic ovary syndrome

Protocol summary

Summary

(1) Objectives: To compare the effects of drugs on oligomenorrhea with Agnogol and metformin in patients with polycystic ovary syndrome (2) Design: The study in women with polycystic ovary syndrome in women with oligomenorrhea referred to feminin Fatemieh clinic ftatemiye hospital , with a sample content of 120 , randomized, double-blind clinical trial, single-center, Phase 2-3 clinical trial will be conducted. (3) How do the population of eligible women, will be the first visit by a gynecologist and then as an entry criteria, Randomized block permutation . The subjects were randomly assigned to two groups: A (group receiving drugAgnogoll) and group B (consumer groups metformin), or other groups taking medication Agnogol and consumer groups like metformin divided,Then for 3 periods are intervention by drugs .Check list before and after the intervention is completed by individuals. (4) inclusion criteria: (1) married; Not pregnant; There oligomenorrhea Exclusion criteria from the study: taking any medications that affect the menstrual cycle; Allergy medication; Taking oral contraceptives (5) interventions: medication Agnogol and metformin for 3 months in each group separately (6) The main outcome : Improve oligomenorrhea

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072623350N1**

Registration date: **2015-09-08, 1394/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-08, 1394/06/17

Registrant information

Name

Arezoo Shayan

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0551

Email address

a.shayan@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Hamadan University of Medical Sciences

Expected recruitment start date

2015-10-24, 1394/08/02

Expected recruitment end date

2016-03-21, 1395/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of the drug agnogol and metformin on oligomenorrhea in patients with polycystic ovary syndrome

Public title

The effect of agnogol on oligomenorrhea in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being married; Being pregnant; There oligomenorrhea; No known physical or mental illness

confirmed by a psychiatrist; Not taking any hormonal medication to treat menstrual disorders in the last three months; No history of allergies to herbal medicines; No drugs affecting the menstrual cycle; Not taking anti-androgen drugs and combinations of estrogen and progesterone secretion and insulin action and insulin and drugs affecting between 1 month before the survey; No history of liver disease, kidney, cardiovascular, diabetes
Exclusion criteria: taking any medications that affect the menstrual cycle; Allergy medication; Drugs and oral contraceptives; Androgen-secreting tumors, high blood prolactin; Unwillingness to cooperate in the project

Age

No age limit

Gender

Female

Phase

2-3

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

Not used

Assignment

Parallel

Other design features

Method of randomization block permutation is a table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Boulevard Martyr Fahmideh, Hamadan University Of Medical Sciences, Hamadan

City

Hamadan

Postal code

Approval date

2015-07-25, 1394/05/03

Ethics committee reference number

IR.UMSHA.REC.1394.230

Health conditions studied

1

Description of health condition studied

Oligomenorrhea

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Improve oligomenorrhea

Timepoint

Before, 3 months after intervention

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Agnogol drug contains extracts of five fingers prescription orally,3.2-4.8 mg 1 times daily After a meal, for 3 month

Category

Treatment - Drugs

2

Description

In intervention group2: Metformin prescription orally,500 mg 3 times daily (totally 1500 mg), for 3 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyeh Hospital

Full name of responsible person

Soghra Rabiee

Street address

Clinic Women, Fatemiyeh Hospital, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Hamadan University of
Medical Sciences

Full name of responsible person

Mohammad Yosef Alikhani

Street address

Street Martyr Fahmideh, Hamadan University Of
Medical Sciences , Hamadan

City

Hamadan

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research, Hamadan 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**

Hamadan University of Medical Sciences

Full name of responsible person

Arezoo.Shayan

Position

Masters, Lecturer Faculty

Other areas of specialty/work**Street address**

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Web page address

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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