

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of additive effect of Fenugreek seed extract on the insulin resistancy in infertile women with polycystic ovarian syndrom

Protocol summary

Summary

Fenugreek and metformin with different mechanisms effect on the FBS and insulin. The objective of the study was to assessment of additive effect of fenugreek seed on the insulin resistancy in infertile women with polycystic ovarian syndrom. This was a prospective randomized, double-blind, placebo-controlled trial. The study was conducted at the Montaserieh Hospital. The patient population was 58 that have inclusion criteria: infertility etiology of ovarian factor, normal function of liver and kidney, FBS<200mg/dl,.... Women were randomly allocated to intervention or control groups and were assessed before and every 4 weeks within a treatment period of 8 weeks. Patients in intervention group used feugreek capsuls of 500mg twice daily and metformin tablets of 500mg three times a day. Patients in control group used placebo capsuls twice daily and metformin tablets like intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810082924N1**

Registration date: **2010-02-02, 1388/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-02, 1388/11/13

Registrant information

Name

Maryam Hassanzadeh Bashtian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2007-11-26, 1386/09/05

Expected recruitment end date

2009-01-08, 1387/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of additive effect of Fenugreek seed extract on the insulin resistancy in infertile women with polycystic ovarian syndrom

Public title

Assessment of effect of Fenugreek seed on the insulin resistancy in the infertile women with polycystic ovarian

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. female infertility, 2. To have two of three criteria for PCOS(oligo/amenorrhea, clinical sign or biochemical hyperandrogenism, PCOS in sonographic view), 3. insulin resistance (FGIR<4.5), 4. FBS<200mg/dl, 5. normal function of liver and kidney(Cr<1.4mg/dl), 6. selected for ovarian stimulation. Exclusion criteria: 1.diabetes mellitus type one, hyperprolactinemia, hypothyroidism, adrenal disorder, abnormal HSG, previous medical disease (septicemia, kidney failure, congestion heart failure, gastrointestinal disorder),

confound drugs to the metformin.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 58

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

Vice chancellor for research of Mashhad University of medical sciences

Street address

Ghoreshi building, Daneshgah street

City

Mashhad

Postal code

Approval date

2007-08-17, 1386/05/26

Ethics committee reference number

85182

Health conditions studied

1

Description of health condition studied

Insulin resistance in infertile women with polycystic ovarian syndrome(PCOS)

ICD-10 code

N99

ICD-10 code description

Other disorders of genitourinary tract

Primary outcomes

1

Description

insulin resistance

Timepoint

End of 8 weeks

Method of measurement

Biochemical and hormonal tests

2

Description

fasting blood sugar (FBS)

Timepoint

End of 8 weeks

Method of measurement

Biochemical test

3

Description

glucose tolerance test of two hours (GTT)

Timepoint

End of 8 weeks

Method of measurement

Biochemical test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hydroalcoholic of fenugreek seeds extract capsules and metformin tablet (Fenugreek capsules of 500mg twice daily and metformin tablets of 500mg three times a day for 8 weeks)

Category

Treatment - Drugs

2

Description

Control group: placebo capsules and metformin tablet (Placebo capsules twice daily and metformin tablets of 500mg three times a day for 8 weeks)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Montaserieh hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mashhad University of medical sciences

Full name of responsible person

Dr jalil Tavakol Afshari

Street address

Ghoreshi bulding - Daneshgah street

City

Mashhad

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 of 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

Maryam Hassanzadeh Bashtian

Position

MSc in midwifery

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

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Person responsible for scientific inquiries

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Maryam Hassanzadeh Bashtian

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****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