Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of addetive 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 addetive 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)

Phone

+98 58 3151 1206

Email address

m.h.bashtian@gmail.com

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 addetive 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 (septecemia, 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
golucose 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: hydroalcholic of fenugreek seeds extract capsuls and metformin tablet (Fenugreek capsuls of 500mg twice daily and metformin tablets of 500mg three times a day for 8 weeks)

Category
Treatment - Drugs

2

Description
Control group: placebo capsuls and metformin tablet(Placebo capsuls 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
Sadaf street, Sadaf 2, No:64
City
Mashhad
Postal code
Phone
+98 51 1867 4826
Fax
Email
bashtian@yahoo.com; M.H.Bashtian@gmail.com
Web page address

Person responsible for scientific 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
Sadaf street, Sadaf 2, No:64
City
Mashhad
Postal code
Phone
+98 51 1867 4826
Fax
Email
bashtian@yahoo.com; M.H.Bashtian@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
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