Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of fenugreek tablets (Moota) with metformin tablets in improving the clinical symptoms and metabolic status of patients with polycystic ovary syndrome (PCOS) referred to the clinics of the University of Medical Sciences

Protocol summary

Study aim
Comparison of Fenugreek Pills (Motta Pills) with Metformin in Improving Clinical Symptoms

Design
Pre-designed questionnaire including demographic variables and laboratory variables studied First, the data are entered into SPSS software version 22 and in order to analyze the data using descriptive statistics methods including frequency distribution tables and graphs, the studied variables will be described and the expression of stratified variables will be compared through a test. Chi-square (Pearson's x2-test) will be performed and also the relationship between continuous variables and if there is a normal distribution using t-test and if there is no normal distribution using Mann-Whitney test will be examined. All tests will be reviewed at an error level of 5%.

Settings and conduct
Patients were treated with pre-determined drug packages by the study supervisor (supervisor). The forms were completed by the project manager and his assistant who were not aware of the contents of the packages; in the data analysis stage, the analysis was performed by the project consultant and the project manager who were not aware of the contents of the drug packages and only the patient group. (Group 1 or 2) was determined for data analysis.

Participants/Inclusion and exclusion criteria
Include: Female infertility (ovarian factor) Exclude: Use of other blood sugar control drugs

Intervention groups
One group will use fenugreek tablets and the second group will use the common drug metformin and the two groups will be compared.

Main outcome variables
Insulin, insulin resistance hair loss Around the abdomen around the waist Menstrual irregularities Hyperlipidemia (total cholesterol, HDL, LDL, triglyceride) Blood sugar BMI Weight Hirsutism score Hormone levels (free testosterone, FSH, LH, dehydroepiandrosterone sulfate, 17-hydroxy progesterone, TSH) blood pressure Complications

General information

Reason for update

Acronym
(PCOS)

IRCT registration information
IRCT registration number: **IRCT20220130053874N1**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **retrospective**

Last update: **2022-10-19, 1401/07/27**
Update count: **0**

Registration date
2022-10-19, 1401/07/27

Registrant information

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Mitra Kazerooni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15
Expected recruitment end date
2022-01-05, 1400/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of fenugreek tablets (Moota) with metformin tablets in improving the clinical symptoms and metabolic status of patients with polycystic ovary syndrome (PCOS) referred to the clinics of the University of Medical Sciences

Public title
Comparison of the effect of fenugreek (Moota) with metformin tablets in improving clinical symptoms and metabolic status of patients with polycystic ovary syndrome (PCOS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Female infertility (ovarian factor) 2. Having two of the three criteria of polycystic ovary syndrome: oligomenorrhea or amenorrhea, clinical or biochemical symptoms of hyperandrogenism, polycystic ovaries in ultrasonographic view. 4. Fasting blood sugar (FBS) less than 200 mg / dL 5. Normal liver and kidney function (serum creatinine less than 1.4 mg / dL)
Exclusion criteria:
History of medical conditions such as diffuse blood infection, renal failure, congestive heart failure, disorders of chemical characteristics of the kidney, gastrointestinal problems. Type 1 diabetes Adrenal disorders Hypothyroidism Use of other blood sugar medications
Age
From **16 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data and Safety Monitoring Board

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization does not guarantee balance in the numbers in the study. In particular, if the patient's characteristics change over time (for example, patients are worse off early than after treatment), the imbalance cannot be corrected early. Block randomization is used to solve this problem. The main idea of randomization of patients is to divide the block into M blocks of size 2N, so that in each block N patients are assigned A and patients N are assigned to B. The block is then randomly selected. This method ensures equal treatment allocation per block provided the block is fully utilized. For example: two treatments A, B and block size 2.2 = 4 Treatment allocation is possible within each block AABB (2) BBAA, (3) ABAB, (4) BABA, (5) ABBA, (6) BAAB The size of the block, depending on the number of treatments, should be short enough to prevent imbalance, and large enough to prevent guessing treatment allocation in each group during the study. The size of the block should be at least twice the number of treatment nodes. The size of the block is not stated in the study so that researchers are blind to it. If the blocks are expressed, the treatment series in each block can be guessed. For example, in block 2N = 4, A A B must be B and in A A as B B can be deduced. This can lead to (selection bias). The solution to prevent this error is to: (1) not reveal the block mechanism. (2). Use random block size.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blinding: Patients are treated with medication packages pre-determined by the study supervisor (supervisor). Drug packages are completely similar in shape and the patient and the project manager are not aware of the contents of the packages. In addition, data collection, patient assessment and completion of forms is done by the project manager and his assistant who are not aware of the contents of the packages; In the data analysis stage, the analysis will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the group of patients (group 1 or 2) will be identified for data analysis; Therefore, the study is three-blind and from the stage of patient entry into the study to the study, data collection and analysis of information, the contents of the two drug groups are not known.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code

333

Approval date
2020-12-19, 1399/09/29

Ethics committee reference number
IR.IUMS.FMD.REC.1399.552

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Improve clinical symptoms

Timepoint
At the beginning of the intervention

Method of measurement
By checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving fenugreek medicine

Category
Treatment - Drugs

2

Description
Control group: Patients receiving Metformin medicine

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospitals of Iran University of Medical Sciences

Full name of responsible person
Shahla Mir Galoo-Bayat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
50

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Shahla Mir Galoo-Bayat

Position
Associate professor

Latest degree
Specialist

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Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Will be published in the article
When the data will become available and for how long
Will be published in the article
To whom data/document is available
Everyone who reads the article
Under which criteria data/document could be used
Will be published in the article
From where data/document is obtainable
Will be published in the article
What processes are involved for a request to access data/document
Will be published in the article
Comments