# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

**Name**

Mitra Kazerooni

**Name of organization / entity**

**Country**

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**
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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
**Other areas of specialty/work**
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**