Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigate the effect of Marrubium Vulgare dry powder of extract on Hormonal parameters and clinical finding in poly cystic ovarian syndrome

Protocol summary

Study aim
Investigate the effect of Marrubium Vulgare dry powder of extract on hormonal parameters and clinical finding in polycystic ovarian syndrome

Design
clinical trial with control group, three-way blind, randomized,with a sample size of 23 people in each group,phase 3, The study plan is N = 1, meaning that a patient is given a treatment such as active therapy or placebo for a short period of time.

Settings and conduct
This study is a three-way blind and randomized that will be performed on patients diagnosed with Polycystic Ovarian Syndrome who referred to the special clinic of Imam Reza hospital. envelopes containing 180 capsules.The 250 mg capsule intervention group will receive the marrubium vulgare twice a day for 2 months. and the placebo control group will receive the same dose as the intervention group.

Participants/Inclusion and exclusion criteria
Normal puberty, Ages between 18 and 35, Not pregnant, Lack of thyroid/adernal/pituitary and ovarian disorders, not using sex steroids, Not history of treatment or surgery for polycystic ovary syndrome

Intervention groups
In the intervention group,250 mg capsules containing the dry extract of marrubium vulgare will be prescribed twice a day for 2 month, and in the control group,similar capsules without herbal medicine will be prescribed in the same number and duration

Main outcome variables
In all patient, blood samples are collected at the beginning of the course and after the end of the treatment period, and the levels of testostron, estadiol and progestrone, as well as cholesterol, triglycerides and fasting blood sugar are evaluated (preliminary result). changes in acne, hirsutism, menstrual irregularities and changes in BMI before and after treatment are also evaluated (secondary out come)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200404046942N1**
Registration date: **2020-04-29, 1399/02/10**
Registration timing: **prospective**

Last update: **2020-04-29, 1399/02/10**
Update count: **0**

Registration date
2020-04-29, 1399/02/10

Registrant information
Name
Fatemeh Sargazi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3651 9853
Email address
sargazif931@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-21, 1399/03/01
Expected recruitment end date
2021-09-23, 1400/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigate the effect of Marrubium Vulgare dry powder of extract on Hormonal parameters and clinical finding in poly cystic ovarian syndrome

Public title

Investigate the effect of Marrubium Vulgare dry powder of extract on Hormonal parameters and clinical finding in poly cystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have a history of normal puberty Thyroid tests are normal Rotterdam criteria for polycystic ovarian syndrome The patients age is between 18 and 35 years Lack of thyroid disorders, Hyperprolactinemia, Hyper gonadotropic hypogonadism, Premature ovarian failure, Cushing´s syndroms, Congenital Adrenal Hyperplasia, Ovarian and Adrenal neoplasms and failure to develop physical illnesses Absence of pregnancy Lack of recent history of surgical treatment for Polycystic Ovarian Syndrome and treatment for Polycystic Ovarian Syndrome Do not use sex steroids(such as birth control pills, hormone therapy and androgenic drugs) and not use chemical and herbal medicines Do not use cigarettes and hookah

Exclusion criteria:

Being pregnant use of sex steroids Suffering from thyroid disorders, hyperprolactinemia, hypergonadotropic hypogonadism, premature ovarian failure, Cushing's syndrome, congenital adrenal hyperplasia, ovarian and adrenal neoplasms, physical illness Having a history of recent treatment for polycystic ovary syndrome Being under 18 years of age or over 35 years of age

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The random assignment list will be created by computet(random number table using sites such as www.randomization.com or Excel software) and divided into two groups based on intervention and control. The method of the envelope is that the envelopes are prepared by a member of the research team and random numbers with the help of the site www.randomization.com and its printing is placed inside the envelope.the envelope door will be closed and its contents will not be visible from the outside,and then the petson will pick up an envelope and enter the control or intervention group based on its contents. The method of concealment of allocation is closed envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is a three-way blind clinical trial in which the subjects,observers and analysts did not know any of the individuals in the study groups.

Placebo

Used

Assignment

Other

Other design features

The design of this study is N = 1, which means that a patient is given a treatment such as active therapy or placebo for a short time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad university of medical sciences

Street address

Deputy of Research and Technology, Qureshi Building, University street, Mashhad, Khorasan Razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.895

Health conditions studied

1

Description of health condition studied

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

In all patients, the level of testosterone is measured at the beginning of the visit and after the end of the

treatment period.

Timepoint

At the begining of the patient´s visit and after the end of the two-month treatment period

Method of measurement

Using blood samples and radioimmunoassay

2

Description

In all patients, the level of estradiol is measured at the beginning of the visit and after the end of the treatment period.

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

Using blood samples and radioimmunoassay

3

Description

In all patients, the progesterone level is measured at the beginning and after the end of the treatment period

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

Using blood samples and radioimmunoassay

4

Description

In all patients, the amount of cholesterol is measured at the beginning and after the end of the treatment period

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

Blood sample

5

Description

In all patients, the amount of triglyceride is measured at the beginning of the visit and after the end of the treatment period.

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

blood sample

6

Description

In all patients, the amount of fasting blood sugar is measured at the beginning of the visit and after the end of the treatment period.

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

blood sample

Secondary outcomes

1

Description

Changes in acne progression before and after treatment are evaluated

Timepoint

At the beginning of the patient´s visit and after the end of the two-month treatment period

Method of measurement

Assessment of hirsutism is performed using its own scurvy

2

Description

Changes in menstrual irregularities are assessed

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

By calculating the menstrual cycle

3

Description

Changes in body mass index before and after treatment are evaluated

Timepoint

At the beginning of the visit and after the end of the two-month treatment period

Method of measurement

Using the formula for calculating body mass index

Intervention groups

1

Description

Intervention group: The intervention group will receive 250 mg capsules of marrubium vulgare plant twice a day for two months.These capsules are made by Mashhad School of Pharmacy.In order to prepare the capsules, the extract from marrubium vulgare plant is converted into granules and then The capsules are filled with granules

Category

Treatment - Drugs

2

Description

Control group: They will receive the placebo control group, which are similar capsules in terms of color with marrubium vulgare capsules and lack effective substance , with the same dose and method of use as the intervention group.The placebo will be provided by Mashhad School of Pharmacy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital Special Clinic

Full name of responsible person
Dr. Maliha Afiat

Street address
Imam Reza Hospital Building, Imam Reza Square, Ibn Sina St., Mashhad, Khorasan Razavi, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3854 3031

Email
emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Vice Chancellor for Research and Technology, Qureshi Building, Daneshgah St., Mashhad, Khorasan Razavi, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 1538

Email
vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Sargazi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Gynecology and Obstetrics

Street address
4th floor, 14th unit,1th block, one saman residential complex, Shahrak Gharb, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3651 9853

Fax

Email
sargazif931@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Sargazi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Gynecology and Obstetrics

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City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3651 9853

Fax

Email
sargazif931@mums.ac.ir

Person responsible for updating data

sargazif931@mums.ac.ir

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Sargazi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
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Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3651 9853

Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available