Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the Effects of DASH and Standard Diets With and Without Curcumin Supplementation on Gene Expression of Interleukin-1 Alpha , 5 Alpha – Reductase, Serum Concentration of Testosterone and Glycemic Indices in Infertile Women With Polycystic Ovary Syndrome Candidate for In Vitro Fertilization (IVF)

Protocol summary

Study aim

Investigate the effects of DASH diet and Curcumin on expression of Interleukin 1 Alpha , 5 Alpha reductase and androgenic and glycemic profile, in women with polycystic ovary syndrome (PCOS)

Design

A randomized, double-blind, placebo-controlled trial, with a 2*2 factorial design; 96 patients will be randomly assigned to four groups using a Stratified Permuted Block Randomization, in equal block sizes of 4; by Package 'blockrand' in R software, 4.0.2 version.

Settings and conduct

Study will be conducted at Yazd Reproductive Sciences Institute; COVID-19 screening,dietary assessing, blood sampling, analysis of body composition and anthropometric indices will be performed; mRNA expression levels, androgenic and glycemic profile will be evaluated by using Real-Time PCR and ELISA methods, respectively. After 12 weeks, all of the above steps will be repeated. Curcumin and placebo will be provided in similar bottles with different letters (A, B; labeled by someone not related to the study); participants and researchers will not be aware of bottles content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women with PCOS, aged 18–40 years, candidate for In Vitro Fertilization; Major exclusion criteria: having metabolic abnormalities, hypertension, cancer and mental illness; taking anti-diabetic, androgenic and contraceptives drugs.

Intervention groups

All participants will receive Curcumin or placebo (500 mg twice daily) plus individual diet (DASH or standard); 1) Curcumin plus DASH diet; 2) Curcumin plus standard diet; 3) Placebo plus DASH diet; 4) Placebo plus standard diet.

Main outcome variables

Expression values of interleukin-1 alpha and 5 alpha – reductase genes; Serum levels of testosterone and 5α-dihydrotestosterone; FBS, insulin and homeostasis model assessment of insulin resistance.

General information

Reason for update

Actual sample size, actual recruitment start date and actual recruitment end date were added.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048731N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **prospective**

Last update: **2024-05-02, 1403/02/13**
Update count: **3**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Tayebeh Zohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14
Expected recruitment end date
2022-07-23, 1401/05/01
Actual recruitment start date
2022-08-23, 1401/06/01
Actual recruitment end date
2023-04-21, 1402/02/01
Trial completion date
empty

Scientific title
Investigation of the Effects of DASH and Standard Diets With and Without Curcumin Supplementation on Gene Expression of Interleukin-1 Alpha , 5 Alpha – Reductase, Serum Concentration of Testosterone and Glycemic Indices in Infertile Women With Polycystic Ovary Syndrome Candidate for In Vitro Fertilization (IVF)

Public title
Effect of diet therapy with and without Curcumin in treatment of Polycystic Ovary Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with PCOS diagnosed according to Rotterdam criteria. Aged 18–40 years Candidate for IVF without previous history of IVF Having a BMI range of 18.5-25 and BMI ≥25 kg/m²
Exclusion criteria:
Metabolic and endocrine abnormalities including thyroid dysfunction, Cushing's syndrome, diabetes or impaired glucose tolerance, hyperprolactinemia, congenital adrenal hyperplasia, liver disease, cardiovascular disease, kidney disease, hypertension, neurological diseases, any history of mental illness, having cancer, autoimmune and inflammatory disorders (rheumatoid arthritis). Smoking by the patient or her spouse Alcohol drinking Taking contraceptives or any other drugs that may affect reproductive physiology (during the three months before the study) Taking anti-diabetic, anti-obesity, estrogenic and androgenic drugs Taking supplements such as vitamin C, vitamin E and omega-3 because of their anti-inflammatory and antioxidant effects, three months before or during the intervention.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **96**
Actual sample size reached: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be assigned to four groups according to the method of Stratified Permuted Block Randomization based on BMI (BMI:18.5-25 and BMI ≥25), in equal block sizes of 4; Therefore, participants will have an equal chance for being in each group. A random allocation list will be created by Package ‘blockrand’ in R software, 4.0.2 version. The intervention groups will be randomly allocated into 4 groups: Group 1: 500 mg Curcumin twice daily and DASH diet, Group 2: 500 mg Curcumin twice daily and standard diet, Group 3: 500 mg Placebo twice daily and DASH diet, Group 4: 500 mg Placebo twice daily and standard diet.
Blinding (investigator's opinion)
Double blinded
Blinding description
Supplements and placebos capsules will be provided in the same appearance (in terms of color and shape) and packed in similar bottles. The bottles will be labeled with different marks (A and B), by someone not related to the study. Each bottle contains 64 capsules (for one month use and two days of grace period). Participants and researchers will not be aware of bottles content. As well as intervention groups will be assigned to receive two healthy dietary patterns (DASH or standard diet). These diets will be designed in the form of an individual diet containing 18 % protein, 52 % carbohydrates, and 30 % total fat. Overall, DASH and standard patterns will be designed using similar foods and recipes, but in different amounts, to achieve the specific characteristics of each diet.The amount of sodium prescribed for each diet will be the same. Two Midwifery experts will check the baseline measurements, a COVID-19 screening, inclusion and exclusion criteria. They will give consecutive numbers to eligible participant and refer them to a nutritionist who is not involved in this study. Participants will receive their specific diet through face-to-face individual counseling. 12- Week menu plans (7-day cycle menu with 21 meals) at eleven energy levels (1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100 and 2200 kcal) for both dietary patterns will be constructed and analyzed. Both diets will be planned by the study dietitian and reviewed by the chief Investigator. These will be considered as the basis for participants' individual diets. Then the specific diet of each person will be calculated. Nutritionist IV software will be used for calculations. In our opinion, this study is double-blind, because all the researchers and final analysts will remain conceal from the allocation and will not be able to distinguish between groups. Participants will only aware of the type of diet but will not know the content of placebo or curcumin supplement.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Science

Street address
Safaeiye Ave., Alam Square., Shahid Sadoughi University of Medical Science., Yazd.

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Yazd

Province
Yazd

Postal code
8915173160

Approval date
2020-09-09, 1399/06/19

Ethics committee reference number
ir.ssu.sph.rec.1399.145

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
Interleukin 1 Alpha gene

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Real time Polymerase Chain Reaction (PCR)

2

Description
5 Alpha reductase gene

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Real time Polymerase Chain Reaction (PCR)

Secondary outcomes

1

Description
Testosterone

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa method

2

Description
5α-dihydrotestosterone

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa method

3

Description
Insulin

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa method

4

Description
Homeostasis model assessment of insulin resistance (HOMA-IR)

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Calculation using HOMA-IR formula

5

Description
Fasting blood sugar

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Enzymatic method

6

Description
Anthropometric indices

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Anthropometric indices will be measure, including weight using calibrated Seca scale with an accuracy of 0.1 kg and a minimum of clothes ; height, waist and hip circumference using a tape measure with an accuracy of 0.5 cm; as well as Body Mass Index and waist-hip ratio

will be calculated.

7

Description

Body composition

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Measurement of body composition, including muscle mass (MM), fat mass (FM), and fat free mass (FFM)], using Bioelectric Impedance Analyzer (BIA)

8

Description

Energy and nutrient intake

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Using 3 Days food record (2 days per week and one day off) and analyzing with Nutritionist 4 software

9

Description

Physical activity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

physical activity questionnaire

Intervention groups

1

Description

"Intervention group 1:" Curcumin capsules and DASH diet; in this intervention group, 24 patients will receive 500 milligrams of Curcumin capsule twice daily and DASH diet for 12 weeks, each person's diet will designed individually. The Dietary Approaches to Stop Hypertension (DASH) diet is a diet that emphasizes vegetables, fruits and low-fat dairy products; and moderate amounts of whole grains, poultry, fish, and nuts; while it contains only small amounts of red meat, sweets, and sugar-containing beverages. The DASH diet will be designed to contain 52 % carbohydrates, 18 % protein, and 30 % total fat; if a person is overweight or obese, the patient's calculated energy will be reduced by 300 and 500 kcal, respectively.12- Week menu plans (7-day cycle menu with 21 meals) at eleven energy levels (1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100 and 2200 kcal) will be constructed and analyzed. These will be considered as the basis for participants' individual diets. Nutritionist IV software (Diet analysis, Module version 3.5.2) will be used for calculations. Participants will receive their specific diet through face-to-face individual counseling, initial assessment and intervention for 45 to 60-minutes with a Registered Dietitian (follow- up visits will take 15 to 30 minutes per month). They will also receive a bottle of capsules (on 1st day, 30th day and 60th day of visit), each bottle containing 64 capsules (providing supplement for 1 month and a grace period of 2 days). Administration instructions on taking the pills and what to do if there is a missed dose will be set for patients, including taking two capsules a day (one after breakfast and one after evening meal with water) and taking the missed capsule the same day. Daily supplementation will be checked by contacting the participants using phone interviews and messaging tools (WhatsApp) twice a day.

Category

Treatment - Drugs

2

Description

"Intervention group 2:" Curcumin capsules and standard diet; in this intervention group, 24 patients will receive 500 milligrams of Curcumin capsule twice daily and standard diet for 12 weeks, each person's diet will designed individually.The standard diet will be designed to contain 52 % carbohydrates, 18 % protein, and 30 % total fat; if a person is overweight or obese, the patient's calculated energy will be reduced by 300 and 500 kcal, respectively.12- Week menu plans (7-day cycle menu with 21 meals) at eleven energy levels (1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100 and 2200 kcal) will be constructed and analyzed. These will be considered as the basis for participants' individual diets. Nutritionist IV software (Diet analysis, Module version 3.5.2) will be used for calculations. Participants will receive their specific diet through face-to-face individual counseling, initial assessment and intervention for 45 to 60-minutes with a Registered Dietitian (follow- up visits will take 15 to 30 minutes per month). They will also receive a bottle of capsules (on 1st day, 30th day and 60th day of visit), each bottle containing 64 capsules (providing supplement for 1 month and a grace period of 2 days). Administration instructions on taking the pills and what to do if there is a missed dose will be set for patients, including taking two capsules a day (one after breakfast and one after evening meal with water) and taking the missed capsule the same day. Daily supplementation will be checked by contacting the participants using phone interviews and messaging tools (WhatsApp) twice a day.

Category

Treatment - Drugs

3

Description

"Intervention group 3:" Placebos capsules and DASH diet; in this intervention group, 24 patients will receive 500 milligrams of placebo capsule twice daily and DASH diet for 12 weeks, each person's diet will designed individually. Placebos capsules will be provided in the similar appearance with curcumin capsules (in terms of color and shape) and packed in same bottles. The DASH diet will be designed to contain 52 % carbohydrates, 18 % protein, and 30 % total fat; if a person is overweight or

obese, the patient's calculated energy will be reduced by 300 and 500 kcal, respectively. 12- Week menu plans (7-day cycle menu with 21 meals) at eleven energy levels (1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100 and 2200 kcal) will be constructed and analyzed. These will be considered as the basis for participants' individual diets. Nutritionist IV software (Diet analysis, Module version 3.5.2) will be used for calculations. Participants will receive their specific diet through face-to-face individual counseling, initial assessment and intervention for 45 to 60-minutes with a Registered Dietitian (follow- up visits will take 15 to 30 minutes per month). They will also receive a bottle of capsules (on 1st day, 30th day and 60th day of visit), each bottle containing 64 capsules (providing supplement for 1 month and a grace period of 2 days). Administration instructions on taking the pills and what to do if there is a missed dose will be set for patients, including taking two capsules a day (one after breakfast and one after evening meal with water) and taking the missed capsule the same day. Daily supplementation will be checked by contacting the participants using phone interviews and messaging tools (WhatsApp) twice a day.

Category

Treatment - Other

4

Description

"Control group:" Placebos capsules and standard diet; in this group, 24 patients will receive 500 milligrams of placebo capsule twice daily and standard diet for 12 weeks, each person's diet will designed individually. The standard diet will be designed to contain 52 % carbohydrates, 18 % protein, and 30 % total fat; if a person is overweight or obese, the patient's calculated energy will be reduced by 300 and 500 kcal, respectively. 12- Week menu plans (7-day cycle menu with 21 meals) at eleven energy levels (1200, 1300, 1400, 1500, 1600, 1700, 1800, 1900, 2000, 2100 and 2200 kcal) will be constructed and analyzed. These will be considered as the basis for participants' individual diets. Nutritionist IV software (Diet analysis, Module version 3.5.2) will be used for calculations. Participants will receive their specific diet through face-to-face individual counseling, initial assessment and intervention for 45 to 60-minutes with a Registered Dietitian (follow-up visits will take 15 to 30 minutes per month). They will also receive a bottle of capsules (on 1st day, 30th day and 60th day of visit), each bottle containing 64 capsules (providing supplement for 1 month and a grace period of 2 days). Administration instructions on taking the pills and what to do if there is a missed dose will be set for patients, including taking two capsules a day (one after breakfast and one after evening meal with water) and taking the missed capsule the same day. Daily supplementation will be checked by contacting the participants using phone interviews and messaging tools (WhatsApp) twice a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Reproductive Sciences Institute

Full name of responsible person

Tayebeh zohrabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Research Deputy of Health Faculty

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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

Yazd 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

2

Sponsor
Name of organization / entity
Iran National Science Foundation
Full name of responsible person
Dr. Eaman Eftekhary
Street address
No. 33, Fifth Ave., North Karegar Ave., Tehran.
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Phone
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Fax
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Email
info@insf.org
Grant name
Grant code / Reference number
99019137
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Tayebeh Zohrabi
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Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
I have not yet decided on this.

When the data will become available and for how long
I have not yet decided on this.

To whom data/document is available
I have not yet decided on this.

Under which criteria data/document could be used
I have not yet decided on this.

From where data/document is obtainable
I have not yet decided on this.

What processes are involved for a request to access data/document
I have not yet decided on this.

Comments