# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 2026

## The effect of high-intensity interval training and nanocurcumin consumption of microRNAs(miRNA) 29a-5P, 93 and Anti Mullerian Hormone(AMH) in infertile women with polycystic ovary syndrome

## Protocol summary

**Study aim**

The goal: whether high-intensity interval training(HIIT) and nanoCurcumin supplementation in infertile women with PCOS causes changes in MicroRNA (miRNA) 29a-5p, 93,Anti Mullerian Hormone (AMH) and Body Mass Index (BMI)?

**Design**

A controlled, single-blind, randomized, phase 3 clinical trial with factorial design, on 40 patients. How to randomize: 40 beads numbered from 1 to 4 are placed in a box. Then one of the beads is randomly took out, and people are classified into different groups based on the number.

**Settings and conduct**

Study place: in Roya infertility center, Qom province; The study population: infertile women with polycystic ovary syndrome; Type of blinding is single blind; The method of blinding will be in a way that the patients will be unaware of their treatment group, and the training-supplement group will receive nanocurcumin and the training-placebo group will receive capsules containing flour.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: infertile women, with PCOS, age between 20-38 years (fertility age). Exclusion criteria: cardiovascular and respiratory disease, use of hormonal drugs

**Intervention groups**

Intervention group 1: high-intensity interval training (HIIT)+ nanocurcumin; Intervention group 2: HIIT + placebo. Intervention group 3: Nano curcumin; Control group: placebo. Training protocol: High-intensity interval training starts with 80% HRmax and ends with 95% HRmax intensity in the last weeks. These exercises are 3 days a week. During the period, participants in intervention group 1 and 3 will take 80 mg capsules of nanocurcumin with a daily dose, and the control group will also use a placebo.

**Main outcome variables**

MicroRNA (miRNA) 29a-5P; MicroRNA 93; Anti Mullerian Hormone(AMH); Body Mass Index (BMI)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231217060434N1**
Registration date: **2024-01-26, 1402/11/06**
Registration timing: **prospective**

Last update: **2024-01-26, 1402/11/06**
Update count: **0**

**Registration date**

2024-01-26, 1402/11/06

**Registrant information**

**Name**

Fateme Talashan

**Name of organization / entity**

The university of Tehran

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-02-20, 1402/12/01

**Expected recruitment end date**

2024-05-20, 1403/02/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of high-intensity interval training and nanocurcumin consumption of microRNAs(miRNA) 29a-5P, 93 and Anti Mullerian Hormone(AMH) in infertile women with polycystic ovary syndrome

**Public title**

The effects of exercise and supplement on infertile women with PCOS

**Purpose**

Basic scienece

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Infertile women Women with PCOS Age between 20 and 38 years (fertility age)

**Exclusion criteria:**

Cardiovascular disease Respiratory disease Using hormonal drugs

**Age**

From **20 years** old to **38 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Forty beads are placed in a box numbered from 1 to 4. After accepting each patient and obtaining informed consent, one of the beads is randomly took out of the box, and people are classified into different groups based on the number on the beads, so that numbers 1 belong to the group of HIIT, numbers 2: nanoCurcumin supplement, Numbers 3: HIIT+nanocurcumin, numbers 4: placebo. In general, this will be done on 40 patients.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The method of blinding will be in a way that the patients will be unaware of their treatment group, and the training-supplement group will receive nanocurcumin and the training-placebo group will receive capsules containing flour.

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Faculty of Physical Education and Sport Sciences - University of Tehran

**Street address**

Faculty of Physical Education and Sport Sciences, between 15th and 16th street, North Kargar street, Tehran

**City**

Tehran

**Province**

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**Postal code**

37 - 88351730

**Approval date**

2023-11-26, 1402/09/05

**Ethics committee reference number**

IR.UT.SPORT.REC.1402.080

## Health conditions studied

### 1

**Description of health condition studied**

Polycystic ovary syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

### 2

**Description of health condition studied**

Female infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

## Primary outcomes

### 1

**Description**

microRNA 29a-5P

**Timepoint**

before the start of the intervention and 3 months after the intervention at the end of the work.

**Method of measurement**

blood test

### 2

**Description**

Anti Mullerian Hormone

**Timepoint**

before the start of the intervention and 3 months after the intervention at the end of the work.

**Method of measurement**

blood test

**3**

**Description**

microRNA 93

**Timepoint**

before the start of the intervention and 3 months after the intervention at the end of the work.

**Method of measurement**

blood test

## Secondary outcomes

**1**

**Description**

Body Mass Index

**Timepoint**

before the start of the intervention and 3 months after the intervention at the end of the work.

**Method of measurement**

BMI formula

## Intervention groups

**1**

**Description**

Intervention group 1: exercise-supplement. Subjects of the exercise-supplement group take one 80 mg capsule of nanocurcumin with a daily dose during the period. High-intensity interval training starts with 80% HRmax and ends with 95% HRmax in the last weeks. These exercises are held 3 days a week and each training session lasts for 30 minutes (5 minutes of warming up, 15 minutes of training, 10 minutes of cooling down) and includes 4 hours. Each set consists of 4 movements, each of which is performed for 30 seconds with high intensity and takes 15 seconds.

**Category**

Other

**2**

**Description**

Intervention group2: Exercise-placebo group. They receive capsules containing flour. Because the exercise + supplement group and the exercise group will both exercise together in the hall, the exercise group will also be given a placebo so that the two groups of patients do not notice the difference between people. High-intensity interval training starts with 80% HRmax and ends with 95% HRmax in the last weeks. These exercises are held 3 days a week and each training session lasts for 30 minutes (5 minutes of warming up, 15 minutes of training, 10 minutes of cooling down) and includes 4 hours. Each set consists of 4 movements, each of which is performed for 30 seconds with high intensity and takes 15 seconds.

**Category**

Other

**3**

**Description**

Intervention group 3: supplementary group. Subjects in the supplement group will take 80 mg nanocurcumin capsules at a daily dose during the period.

**Category**

Treatment - Drugs

**4**

**Description**

Control group: Also, the control group will use a placebo (containing flour, but if not used, the people in the control group will be prone to celiac disease).

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Rouya Infertility Center

**Full name of responsible person**

Leila naserpor

**Street address**

Rouya center for infertility treatment, Shabnam street, Shahid Karimi Blvd., Qom

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Faculty of Physical Education and Sport Sciences - University of Tehran

**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Faculty of Physical Education and Sport Sciences - University of Tehran

**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**

Iranian academic center for education culture and research

**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Rouya Infertility Center

**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**

The University of Qom

**Full name of responsible person**

Amir hossain Delshad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
Due to participants' demands and the condition of this matter to participate in the project and to protect their privacy, the data will be preserved, but in case of reasonable request from the relevant organizations or people, the information of the project will be 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