

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 25 3289 6680

Email address

fateme.talashan@ut.ac.ir

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 science

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

Tehran

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

City

Qom

Province

Ghoum

Postal code

3716986466

Phone

+98 25 3210 4000

Email

rooyaivfacecrqom@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Physical Education and Sport Sciences - University of Tehran

Full name of responsible person

Mohammad Reza Kordi

Street address

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

City

Tehran
Province
Tehran
Postal code
37 - 88351730
Phone
+98 21 8835 1730
Email
infosport@ut.ac.ir
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
Leila Naserpor
Street address
Rouya center for infertility treatment, Shabnam
street, Shahid Karimi Blvd., Qom
City
Qom
Province
Ghoum
Postal code
3716986466
Phone
+98 25 3210 4000
Email
rooyaivfacecrqom@gmail.com
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
Street address
After Quds settlement, Al-Ghadir Boulevard, Qom
City
Qom
Province
Ghoum
Postal code
3716146611
Phone
+98 25 3210 3693
Fax
Email
ah_delshad@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
The University of Tehran
Full name of responsible person
Mohammad reza kordi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Exercise physiology
Street address
Faculty of Physical Education and Sport Sciences,
between 15th and 16th street, North Kargar street,
Tehran
City
Tehran
Province
Ghoum
Postal code
37 - 88351730
Phone
+98 21 8802 1527
Fax
Email
mrkordi@ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

The University of Tehran

Full name of responsible person

Fateme Talashan

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

Street address

No.60, Jomhoori tower, Shahroz street, Jomhoori street.

City

Qom

Province

Ghoum

Postal code

3716819964

Phone

+98 25 3289 6680

Fax**Email**

fateme.talashan@ut.ac.ir

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