

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effects of High Intensity Interval Training(HIIT) with Nano Curcumin Supplementation on MDA,SOD,GPX,TAC, LH,FSH,TT and Oocytes Maturation , Embryos Quality in Patients with PCOs Undergoing ICSI treatment. a Randomized Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Effect of a High-Intensity Exercise Training Course with Nanomicelle Curcumin Supplementation on Plasma Hormonal and Biochemical Factors, Oocyte Maturation Rate, and Embryo Quality in Infertile Women with Polycystic Ovary Syndrome Undergoing Microinjection Treatment.

Design

A clinical trial with a control group, with a parallel group, a blind strain, randomized, phase 3 on 40 patients

Settings and conduct

Infertile Women With Polycystic Ovary Syndrome under the Supervision of a Gynecologist are Included in the Groups of Medicine, Exercise, Medicine along with Exercise or Control. Before and After the Treatment, Blood Samples are Taken from the Patient to Measure Biochemical Markers. The Place of the Study is in the Infertility Treatment Center of Qom University Jihad.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Periodontal Disorders (Oligomenorrhea or Amenorrhea Patients). Hirsutism, Infertility, Increased LH / FSH Ratio, Ultrasound Findings of Ovarian Size and Multiple Follicles with 2-10 mm Size, Normal Sperm Analysis, Normal Thyroid Function and Prolactin Level, No Endometriosis Exclusion Criteria: No Ovulation, Male Factor Infertility, Pelvic Organ Damage, Congenital Adrenal Hyperplasia, Thyroid Dysfunction, Cushing's Syndrome, Drug Sensitivity And Inability to Exercise.

Intervention groups

Control Group: Metformin for 12 Weeks, 3 Tablets of 500 mg Daily Intervention Group 1: for 12 Weeks Nano Micellar Curcumin (80 mg per day) + 3 Metformin Doses of 500 mg Daily Intervention Group 2: for 12 Weeks Nanomicelle Curcumin (80 mg per day) + 3 Metformin Doses of 500 mg Daily for 12 Weeks along with Exercise Intervention group 3:Metformin for 12 Weeks, 3 Tablets

of 500 mg Daily along with Exercise

Main outcome variables

Sex Hormones, Oxidative Stress, Oocyte Maturation, Embryo Number, Embryo Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210207050279N1**

Registration date: **2024-01-10, 1402/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-10, 1402/10/20**

Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

Name

elham elham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 3987

Email address

asa.elham@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-31, 1402/10/10

Expected recruitment end date

2024-08-31, 1403/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of High Intensity Interval Training(HIIT) with Nano Curcumin Supplementation on MDA,SOD,GPX,TAC, LH,FSH,TT and Oocytes Maturation , Embryos Quality in Patients with PCOs Undergoing ICSI treatment. a Randomized Placebo-Controlled Clinical Trial

Public title
Modification of Complications Caused by Polycystic Ovary Syndrome by Nano Curcumin Drug and HIIT Exercise in Women Undergoing ICSI Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Period Disorders Hirsutism Infertility Increased LH/FSH ratio Ultrasound View in the form of Enlarged Ovaries Having Numerous Follicles with a Size of 2-10 mm The Normality of Sperm Analysis Normal Thyroid Function No Endometriosis Normal Prolactin Level Normal Hysterosalpingography
Exclusion criteria:
Infertility Factors other than Ovulation Male factor infertility Pelvic Organ Injuries Congenital Adrenal Hyperplasia Thyroid Dysfunction Cushing Syndrome Severe Liver or Kidney Diseases Active Gastric Ulcer Drug Sensitivity Intolerance of Exercise

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
40 Beads are Placed in a Box, which are Numbered From 1 to 4. After Accepting Each Patient and After Obtaining Informed Consent, The Treating Physician Randomly Removes one of the Beads Inside the Box (without Seeing the Contents of the Box) and in this Way, People are Classified Into Different Groups, so that Numbers 1 belong to the HIIT Training Group, Numbers 2: Nano Curcumin Supplement, Numbers 3: HIIT and Curcumin Supplement, Numbers 4: Control Group.

Blinding (investigator's opinion)
Double blinded

Blinding description

The Gynecologist was Fully Informed by the Project Manager about Nano Curcumin Drug and the Properties and Side Effects of the Drug. Patients were Placement in the Control and Treatment Group is the Responsibility of The Gynecologist. Patients Who Entered the Project with Full Consent, but Do not Know Whether They will be Placed in the Control or Treatment Group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom University of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran
City
Tehran
Province
Tehran
Postal code
1467664961

Approval date
2023-11-27, 1402/09/06

Ethics committee reference number
IR.MUQ.REC.1402.194

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
Regulation of Sex Hormones

Timepoint
Before Taking the Drug and 12 weeks After Starting to Take the Drug

Method of measurement
Elisa Kit

2

Description

Stress Oxidative Level

Timepoint

Before Taking the Drug and 12 weeks After Starting to Take the Drug

Method of measurement

Laboratory Kits

3

Description

Oocyte and Embryo Quality

Timepoint

After Completing the Intervention

Method of measurement

Shape and Morphology

Secondary outcomes

1

Description

Pregnancy Rate

Timepoint

2 Weeks After Embryo Transfer

Method of measurement

Laboratory kits

Intervention groups

1

Description

Intervention Group: Curcumin Nano Micelle Capsule (80 mg Daily for 12 Weeks) and Metformin (500 mg Daily for 12 weeks)

Category

Treatment - Drugs

2

Description

Intervention group: HIIT Exercise (Three Sessions Per Week) and Nanomicelle Curcumin (80 mg daily for 12 weeks) and Metformin (500 mg Daily for 12 Weeks)

Category

Treatment - Drugs

3

Description

Intervention group: HIIT Exercise (Three Sessions per Week) and Metformin (500 mg per Day for 12 Weeks)

Category

Treatment - Drugs

4

Description

Control group: Metformin, 500 mg Three Times a Day for 12 Weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Treatment Highly Specialized Center Of ACECR Qom

Full name of responsible person

Elham Asa

Street address

No 10, Floor 3, B3 Unit, Razi Building, Razi Alley, Shahid Karimi Blvd

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Qom

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3739164393

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+98 25 3336 8378

Email

asa.elham@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Leila Naserpoor

Street address

Infertility Center of Qom University of Medical Sciences, Shabnam Ave., Isar Town, Shahid Karimi Blvd.

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37131899934

Phone

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Email

leilanasery@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian academic center for education culture and research

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Elham Asa
Position
Embryologist
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Unit 10, 3rd Floor, Razi Building, Razi Alley, Shahid Karimi Blvd
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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)

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

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

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

Title and more details about the data/document

Except for Personal Data, other Outcomes and Variables can be Shared.

When the data will become available and for how long

6 Months After Printing the Results

To whom data/document is available

Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

Providing Accurate Information to a Gynecologist for the

Treatment of Infertility and Welfare of Patients.

From where data/document is obtainable

Elham Asa(09127541614)Asa.Elham@gmail.com

What processes are involved for a request to access

data/document

Access Data by Reading the Article. In Case of Request for More Information, Contact the Project Manager.

Comments