

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of lifestyle education program and conventional treatment compared to conventional treatment alone on premature ovarian failure: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of lifestyle education program and conventional treatment compared to conventional treatment alone on premature ovarian failure

Design

This is a randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Comprehensive Health Centers in Hamadan city, involving 60 eligible patients with premature ovarian failure. The patients will be randomly assigned to the intervention and control groups through the block randomization. However, it should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 30 to 45 years; Premature ovarian failure; High FSH levels; High AMH levels; Being literate. Exclusion criteria: Pregnancy; Using alcohol or cigarette; Using hormonal medications; Uterine or ovarian abnormalities; Psychiatric disease; Sleep disorder

Intervention groups

Intervention group: Routine treatment plus a lifestyle training session once a week for 4 weeks (including lifestyle modification, sleep pattern modification, ways to reduce and control stress, improve nutrition and healthy eating, plan for exercise and physical activity). Control group: Just routine treatment

Main outcome variables

Follicle-stimulating hormone (FSH); Luteinizing Hormone (LH); lifestyle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N485**

Registration date: **2023-10-05, 1402/07/13**

Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**

Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of lifestyle education program and conventional treatment compared to conventional treatment alone on premature ovarian failure: a randomized clinical trial

Public title

The effect of lifestyle education program on premature ovarian failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 30 to 45 years Premature ovarian failure High FSH levels High AMH levels Literate

Exclusion criteria:

Pregnancy Using alcohol or cigarette Using hormonal medications Uterine or ovarian abnormalities Psychiatric disease Sleep disorder

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

65157838695

Approval date

2023-08-26, 1402/06/04

Ethics committee reference number

IR.UMSHA.REC.1402.426

Health conditions studied**1****Description of health condition studied**

Premature ovarian failure

ICD-10 code

E28.3

ICD-10 code description

Primary ovarian failure

Primary outcomes**1****Description**

The level of FSH hormone

Timepoint

Before the intervention and one month later

Method of measurement

With blood sampling and laboratory diagnosis

2**Description**

The level of LH hormone

Timepoint

Before the intervention and one month later

Method of measurement

With blood sampling and laboratory diagnosis

3**Description**

Lifestyle

Timepoint

Before the intervention and one month later

Method of measurement

Using the Walker Health Promotion Lifestyle Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus a lifestyle training session once a week for 4 weeks (including lifestyle modification, sleep pattern modification, ways to reduce and control stress, improve nutrition and healthy eating, plan for exercise and physical activity)

Category

Treatment - Other

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Zahra Bahrami Hadid

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

abasbabai1329@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Bahrami Hadid

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

abasbabai1329@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Marzieh Otogara

Position

Health Promotion Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

m_otogara@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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