

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of lifestyle counseling versus control group on premature ovarian insufficiency in infertile women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of lifestyle counseling versus control group on premature ovarian insufficiency in infertile women

Design

This is a randomized clinical trial with control group, in which 72 eligible patients will be randomly assigned through the drawing a lot to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemieh Hospital in Hamadan city on eligible infertile women with premature ovarian insufficiency. The patients will be randomly assigned to the intervention and control groups through the drawing a lot. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 45 years old; Being married; Reduced ovarian size and volume; Increased FSH and decreased AMH levels; Exclusion criteria: Polygamy of the husband; Psychological disorders; Sexual dysfunction; Hormone use within the past 6 months.

Intervention groups

Intervention group: Routine treatment plus weekly lifestyle modification counseling sessions for 8 sessions
Control group: Routine medical care

Main outcome variables

Primary outcome: The lifestyle, the size and volume of the ovaries and follicles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N477**

Registration date: **2023-07-24, 1402/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-24, 1402/05/02**

Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lifestyle counseling versus control group on premature ovarian insufficiency in infertile women: a randomized clinical trial

Public title

Effect of lifestyle counseling versus control group on premature ovarian insufficiency in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 45 years old Being married
Reduced ovarian size and volume Increased FSH and decreased AMH levels

Exclusion criteria:

Polygamy of the husband Psychological disorders Sexual dysfunction Hormone use within the past 6 months.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring to every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

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, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.UMSHA.REC.1402.279

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The lifestyle

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Using the Walker's Health Promotion Lifestyle Questionnaire

2

Description

The size and volume of the ovaries and follicles

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Using ultrasound imaging

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus weekly lifestyle modification counseling sessions for 8 sessions (including: the impact of physical activity on hormone balance, ways to control stress and its relationship with hormonal disorders and lack of ovulation, exercise techniques to manage stress such as yoga and light walking, understanding the role of nutrition in premature ovarian failure, eliminating carbohydrates and harmful foods, substituting with healthier food options, ways to lose weight without starving, understanding suitable sleeping patterns, identifying the root causes of sleep disorders, and coping strategies for anxiety)

Category

Treatment - Other

2

Description

Control groupRoutine medical care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Mehrnoosh Hosseinpur

Street address

Fatemieh Hospital, Pasdaran Ave.

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6517838695

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+98 81 3838 0572

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

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

Mehrnoosh Hosseinpur

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Farideh Kazemi

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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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

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Email

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