

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of three high animal protein diet , high plant protein and common protein on indicators related to ovarian aging (premature menopause) in people at risk of premature ovarian failure: a clinical trial

Protocol summary

Study aim

Comparison of the effect of three diets of animal protein, plant protein and common protein on the indicators associated with ovarian aging (premature menopause) in people at risk of premature ovarian failure: a clinical trial

Design

Clinical trial with control group, 2 intervention groups, no blinding, blocked randomized with STATA software .

Settings and conduct

The disease will be treated first, then all three groups will be subjected to special diets for each group. At the beginning and end of the study, the necessary exams will be held there. The study site in Khorramabad city is one of the women's specialist offices

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Women aged 20-40 years in whom menstruation has stopped or two to three periods per year occur in them and the level of antimullerian hormone in them is according to the table in the scientific definitions and the level of FSH in them is above IU / L 10 are at risk for premature menopause. 2. Normal creatine level (1-1.2 mg / dl) or GFR above 70 ml / min 3. No change in supplements (vitamins C and E) 4. Conscious consent to participate in the study Exclusion criteria 1. Having a history of ovarian surgery 2- Having a history of radiotherapy

Intervention groups

The present patients are divided into 3 groups based on body mass index: normal, overweight and obese, and then are randomly assigned to each of these intervention groups. The randomization method is described in the statistical section. These patients generally get 25% of their diet from protein. Group 1: Diet includes 15% animal protein and 10% plant protein. The second group is on a diet of 15% plant protein and 10% animal protein and the third group is on a normal diet (15% mixture of

plant protein and animal protein) for 6 months.

Main outcome variables

Anti Mullerian Hormone(AMH) Estrogen Inhibin A Inhibin B

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201124049481N1**

Registration date: **2021-08-12, 1400/05/21**

Registration timing: **prospective**

Last update: **2021-08-12, 1400/05/21**

Update count: **0**

Registration date

2021-08-12, 1400/05/21

Registrant information

Name

marjan bedakhanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3380 3531

Email address

marjanbadakhanian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-21, 1401/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of three high animal protein diet , high plant protein and common protein on indicators related to ovarian aging (premature menopause) in people at risk of premature ovarian failure: a clinical trial

Public title
Comparison of the effect of high protein diet in people at risk of premature menopause

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women in their 20s and 40s who have stopped menstruating or two to three periods a year and have Anti Mullerian hormone level as defined in the scientific definitions and FSH level above 10 IU / L. are at risk for premature menopause Normal creatine or GFR levels above 70 No change in supplements (antioxidants)
Informed consent to participate in the study

Exclusion criteria:

Having a history of radiotherapy Having a history of ovarian surgery

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done in a stratified manner using random permutation blocks. For this purpose, first individuals are classified based on body mass index and then for each category using random block method of individuals in two groups of intervention and a control Will be appointed. The randomization unit is individual. Statistical software is used for randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institute of Nutrition and Food Industry

Street address

No. 7, Shahid Hafezi St. (West Purple), Shahid Farahzadi Blvd.

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2021-05-12, 1400/02/22

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1400.019

Health conditions studied

1

Description of health condition studied

Premature menopause

ICD-10 code

E28.31

ICD-10 code description

Premature menopause

Primary outcomes

1

Description

Serum level of Anti Mullerian Hormone

Timepoint

It will be measured at the beginning and end of the study

Method of measurement

It will be measured by ELISA method

Secondary outcomes

1

Description

Premature menopause

Timepoint

Not applicable

Method of measurement

Based on the AMH level according to the table mentioned in the

2

Description

Serum level of Estrogen

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

3

Description

Serum level of Progesteron

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

4

Description

Serum level of Follicle-stimulating hormone (FSH)

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

5

Description

Serum level of Luteinizing Hormone (LH)

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

6

Description

Serum level of Inhibin A

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

7

Description

Serum level of Inhibin B

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

8

Description

Serum level of C-Reactive Protein

Timepoint

At the beginning and 6 months after starting the diet

Method of measurement

It will be measured by ELISA method.

9

Description

Sonography

Timepoint

At the beginning and end of the study in terms of ovarian volume, number of antral follicles, antral thickness

Method of measurement

Ultrasound device

Intervention groups

1

Description

Group 1: Animal high protein diet

Category

Lifestyle

2

Description

Intervention group: Intervention group: high protein plant diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of obstetricians and gynecologists

Full name of responsible person

Marjan bedakhanian

Street address

City

Khoram abad

Province

Lorestan

Postal code

Phone

+98 21 2237 6471

Fax

+98 21 2209 7419

Email

marjanbadakhanian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr parvin mirmiran

Street address

No. 7, Hafezi St., Shahid Farahzadi Blvd., Ghods Town (West), Tehran, Iran Institute of Nutrition and Food Industry Research

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2209 7419

Email

nnftric@gmail.com

Grant name

ندارد

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

25

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marjan bedakhanian

Position

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No. 7, Hafezi St., Shahid Farahzadi Blvd., Ghods Town (West), Tehran, Iran Institute of Nutrition and Food Industry Research

City

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Postal code

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Phone

0000000

Email

marjanbadakhanian@ymail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marjan bedakhanian

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Phone

00000000

Email

marjanbadakhanian@ymail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marjan bedakhanian

Position

Student

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

=====

When the data will become available and for how long

Up to two months after the end of the intervention

To whom data/document is available

Professors and students in the field of nutrition

Under which criteria data/document could be used

or more extensive research on this disease

From where data/document is obtainable

To Shahid Beheshti School of Nutrition, Dr. Mirmiran

What processes are involved for a request to access data/document

Must be approved by the supervisor Dr. Mirmiran

Comments