Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

The effect of profertility dietary intervention on assisted reproduction outcomes: A randomized controlled trial

Protocol summary

Study aim
To determine the effect of profertility dietary intervention on assisted reproductive technology outcomes in infertile couples by a randomized controlled trial

Design
Randomized double-blind parallel group controlled trial on 180 couples seeking infertility treatments. Randomization by permuted block randomization

Settings and conduct
Participants will be recruited from Hazrat Maryam infertility center by purpose sampling and be allocated in one of the intervention or control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 to 42 years in women; BMI between 20 to 30 kg/m2; consent to participate. Exclusion criteria: current or previous use of oral contraceptive pills, hormone therapy, insulin sensitizers or antidiabetics, weigh reducing agents and dietary supplements; history of chronic and endocrine disorders; history of having more than 2 unsuccessful ART cycles; adherence to specific diets or exercise programs; tobacco or alcohol use; infertility due to tubal or uterine disorders; consumption of more than 2 servings of fatty fish per week; having less than 80 percent compliance for the intervention; change in dietary or physical activity habits due to any reasons.

Intervention groups
Intervention in women in the intervention group includes supplementation with folate, vitamin B12, vitamin D and omega-3 fatty acids, consumption of low- rather than high-pesticide residue fruit and vegetables, whole grains, diary and soy foods. Women in the control group will be provided by healthy eating index recommendations. Men in the intervention group will be asked to decrease the intake of soy foods, caffeine, processed meat, saturated and trans fatty acids and high-pesticide residue fruit and vegetables. Also to increase the consumption of seafoods.

Main outcome variables
Assisted reproductive technology outcome

General information

Reason for update
The information registered in the IRCT was found to be incomplete compared to the approved proposal (which had obtained the ethical approval code)

Acronym

IRCT registration information
IRCT registration number: **IRCT20130903014551N13**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2025-05-20, 1404/02/30**
Update count: **1**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Mohammad Hossein Rouhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of profertility dietary intervention on assisted reproduction outcomes: A randomized controlled trial

Public title
The effect of adherence to profertility diet on assisted reproduction outcomes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 42 years BMI between 20 to 30 kg/m2 Consent to participate
Exclusion criteria:
Current or previous (within three months) drug use including oral contraceptive pills, hormone therapy, insulin sensitizers or antidiabetics, weight reducing compounds and dietary supplements History of chronic and endocrine disorders including diabetes and impaired glucose tolerance History of having more than 2 unsuccessful ART cycles Adherence to specific diets or exercise programs Tobacco or alcohol consumption Infertility due to tubal or uteri disorders Consumption of more than two servings of fatty fish per week
Age
From **18 years** old to **42 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **360**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of infertile couples to either intervention or control groups will be done by permuted blocked randomization with the help of 4 blocking. The process will be conducted using a valid random number generation website. (http://www.sealedenvelope.com/simple-randomiser/v1/lists) The randomized allocation and assignment of participants into intervention groups will be performed by a trained person who is not involved in the trial.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants will be blinded to the intervention
Placebo
Not used
Assignment
Parallel
Other design features
In the present study the intervention will be done based on the components of profertility diet. One of these components is dietary supplementation by high dose folate, vitamin B12, vitamin D and omega-3 fatty acids

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences-Research Ethics Committee of the Alzahra
Street address
Isfahan University of Medical Sciences, Hezar-Jerib st., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.ARI.MUI.REC.1402.091

Health conditions studied

1

Description of health condition studied
Female Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

2

Description of health condition studied
Male infertility
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
Clinical pregnancy rate
Timepoint
At the end of the assisted reproductive technology cycle
Method of measurement
The presence of an intrauterine pregnancy confirmed by ultrasound at 6 weeks’ gestation

Secondary outcomes

1

Description
Endometrial thickness and antral follicle count
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
Transvaginal sonography

2

Description
The number of retrieved, metaphase 2 and normal morphology oocytes
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
By embryologist

3

Description
Fertilization rate
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
The ratio of oocytes that reached the two-pronucleate (2PN) stage to the number of metaphase II (MII) oocytes

4

Description
Embryo formation rate
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
The ratio of embryos to oocytes with two pronuclei

5

Description
Embryo grade based on Scott criteria
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
By embryologist

6

Description
The number of transferred embryos
Timepoint
At the end of the intervention and within ART cycle
Method of measurement
By infertility specialist

7

Description
Biochemical pregnancy rate
Timepoint
At the end of the ART cycle
Method of measurement
A serum b-human chorionic gonadotropin level >6 mIU/mL, typically measured 17 days (range,15 to 20 days) after egg retrieval

8

Description
Sperm quality parameters
Timepoint
At baseline and at the end of the trial
Method of measurement
By infertility specialist

9

Description
Serum folic acid level
Timepoint
At baseline and at the end of the trial
Method of measurement
Electrochemiluminescence immunoassay method

10

Description
Serum B12 level
Timepoint
At baseline and at the end of the trial
Method of measurement
Electrochemiluminescence immunoassay method

11

Description
Serum vitamin D level
Timepoint
At baseline and at the end of the trial
Method of measurement
کروماتوگرافی مایع با کارایی بالا-طیف‌سنجی جرمی

Intervention groups

1

Description
Intervention group: the intervention in women will be as follows; supplementation with folate 1 mg/day, vitamin B12 500 mcg/day, vitamin D 1000 IU/day and omega-3 fatty acids 1000 mg/day- At least 4 servings/day from low-pesticide residue fruit and vegetables- maximum 1 serving/day of high-pesticide residue fruit and vegetables- education to consume whole grain cereals instead of simple or refined carbohydrates- at least 2.5 servings/day of dairy- at least 1 serving/day soy or soy products. The intervention in men will be as follows: to decrease the consumption of soy or soy products, caffeinated beverages, processed meat and saturated and trans fatty acids- to decrease the consumption of high-pesticide residue fruit and vegetables (max 1 serving/day)- to increase the consumption of seafoods. For each participant, energy requirements will be

estimated by Harris-Benedict formula, based on a isocaloric diet. A dietitian will organize a weekly dietary plan for each participant with 15 to 20% of calorie comes from proteins, 25 to 30% from fats and 55 to 60% from carbohydrates.

Category

Treatment - Other

2

Description

Control group: women in the control group will be provided by dietary recommendations based on healthy eating plate. They also will consume 400 mcg/day folate. Men in the control group will be provided by dietary recommendations based on Healthy eating plate as well. For each participant, energy requirements will be estimated by Harris-Benedict formula, based on a isocaloric diet. A dietitian will organize a weekly dietary plan for each participant with 15 to 20% of calorie comes from proteins, 25 to 30% from fats and 55 to 60% from carbohydrates.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Saint Maryam Fertility and Infertility center, Shahid-Beheshti Women' hospital

Full name of responsible person

Rahele Ziaei

Street address

Hazrat Maryam Fertility and Infertility Center, Shahid-Beheshti Women' hospital,Motahhari st., Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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Vice Chancellor for Research, Isfahan University of Medical Sciences, Isfahan, Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Rahele Ziaei

Position

PhD of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Hossein Rouhani

Position
Assistant professor of Community Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
PhD of Nutritional Sciences

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Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data relating to primary and secondary outcomes is available upon reasonable request

When the data will become available and for how long
Data will be available after publication of the results

To whom data/document is available
Investigators from academic or scientific institutes

Under which criteria data/document could be used
Research projects from academic institutes

From where data/document is obtainable
Principal investigators of the research project including Mohammad Hossein Rouhani and Rahele Ziaei

What processes are involved for a request to access data/document
Contact by sending request to principal investigators

Comments