# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jul 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)
**Phone**
+98 31 3792 3183
**Email address**
s_m_rouhani2003@yahoo.com

**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

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3234 6338

**Email**

sm_rouhani@nutr.mui.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Askari

**Street address**

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

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**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

**Street address**

School of Nutrition and Food Science, Isfahan University of Medical Sciences, Isfahan, Iran

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 913 305 1052

**Email**

r.ziaei92@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Rouhani

**Position**
Assistant professor of Community Nutrition

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

**Street address**
School of Nutrition and Food Science, Isfahan University of Medical Sciences, Isfahan, Iran

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Phone**
+98 913 327 6157

**Email**
sm_rouhani@nutr.mui.ac.ir

## Person responsible for updating data

**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

**Street address**
School of Nutrition and Food Science, Isfahan University of Medical Sciences, Isfahan, Iran

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Phone**
+98 913 305 1052

**Email**
r.ziaei92@gmail.com

## 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**