

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Investigation the effect of modified diet on semen factors in men with idiopathic infertility: A randomized clinical trial

#### Protocol summary

##### Study aim

Determining the effect of modified diet on semen factors in men with idiopathic infertility

##### Design

A randomized, controlled, parallel-group, unblinded clinical trial on 66 patients. The codes of Random Allocation Software (RAS) were used for randomization.

##### Settings and conduct

Eligible patients referred to Mehr infertility treatment center (Rasht, Gilan) are randomly divided into two groups of 33: intervention and control. The food record questionnaire to measure and control macronutrients intake in the diet, and physical activity record to calculate the energy expenditure will be evaluated in beginning and every two weeks during the study. Ten milliliter fasting blood and semen samples after 2-3 days of sexual abstinence will be taken from all subjects at the beginning and end of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Oligoasthenoteratozoospermic men aged 20 to 45 years with semen volume > 1.5 ml, BMI equal to 18.5-30, normal testicular volume, normal karyotype and normal levels of FSH, LH and prolactin will be included in the study. And exclusion criteria: consumption of tobacco, alcohol and drugs in the last three months, Y-chromosome microdeletion, more than 25% DNA fragmentation rate, following any special diet during the last three months, taking multivitamin and mineral supplements during the last three months, the presence of uncontrolled inflammatory and chronic diseases such as diabetes, hypothyroidism, history of cancer or pelvic chemotherapy or radiotherapy, untreated varicocele, and prostatitis.

##### Intervention groups

The control group will be given a diet based on height and weight with the modification of the percentage of macronutrients, and for the intervention group, a diet for fertility improvement will be designed according to the individual's height and weight.

#### Main outcome variables

Semen analysis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230514058181N1**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **prospective**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

##### Registration date

2023-05-24, 1402/03/03

##### Registrant information

##### Name

Fatemeh Taheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 5975

##### Email address

ftaheri@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-01, 1402/03/11

##### Expected recruitment end date

2024-05-31, 1403/03/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Investigation the effect of modified diet on semen factors in men with idiopathic infertility: A randomized clinical trial

## Public title

Investigation the effect of modified diet on semen factors in men with idiopathic infertility

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 20 to 45 years Semen volume > 1.5 ml BMI of 18.5-30 Normal testicular volume Normal karyotype Normal level of LH, FSH and prolactin

### Exclusion criteria:

Consumption of tobacco, alcohol and drugs in the last three months Y-chromosome microdeletion More than 25% DNA fragmentation rate Following any special diet during the last three months Taking multivitamin and mineral supplements during the last three months The presence of uncontrolled inflammatory and chronic diseases such as diabetes and hypothyroidism History of cancer or pelvic chemotherapy or radiotherapy Untreated varicocele Prostatitis

## Age

From **20 years** old to **45 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **66**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Balanced block randomization method is used to randomly assign participants into two groups. At first, the randomization sequence based on blocks of 2 and 4 is randomly determined using the software codes of RAS: Random Allocation Software. Then, the eligible people included in the study will be assigned to one of the two groups based on the randomization sequence.

## 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

Gilan University of Medical Sciences (Research Ethics Committee)

##### Street address

Department of Research and Technology of Gilan University of Medical Sciences, in front of 17 Shahrivar Hospital, Shahid Siyadati St., Namjo St.

##### City

Rasht

##### Province

Guilan

##### Postal code

4144666949

#### Approval date

2023-04-19, 1402/01/30

#### Ethics committee reference number

IR.GUMS.REC.1402.034

## Health conditions studied

### 1

#### Description of health condition studied

Idiopathic oligoasthenoteratozoospermia

#### ICD-10 code

N46.9

#### ICD-10 code description

Male infertility, unspecified

## Primary outcomes

### 1

#### Description

Semen analysis

#### Timepoint

The beginning and end of the study

#### Method of measurement

A combination of two eye methods and computer software

## Secondary outcomes

### 1

#### Description

Malondialdehyde

#### Timepoint

The beginning and end of the study

#### Method of measurement

ELISA

### 2

#### Description

Testosterone

**Timepoint**

The beginning and end of the study

**Method of measurement**

ELISA

**Intervention groups****1****Description**

Intervention group: For the intervention group, a fertility-improving diet is designed according to the person's height and weight, with an emphasis on effective foods such as saffron, omega-3, and consuming more vegetable proteins than animal proteins within the permissible limits set for each person.

**Category**

Treatment - Other

**2****Description**

Control group: The amount of calories and the percentage of macronutrients are determined based on the Mifflin formula according to their height, weight and physical activity and the range of acceptable distribution of macronutrients for each person.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mehr infertility treatment center

**Full name of responsible person**

Marziye Mehr Afza

**Street address**

Mehr infertility treatment center, Irshad St., Shahid Ansari Boulevard

**City**

Rasht

**Province**

Guilan

**Postal code**

4178613111

**Phone**

+98 13 3375 5353

**Email**

elmira.hosseinzadeh@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mehr infertility treatment center

**Full name of responsible person**

Marziye Mehr Afza

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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**

Mehr infertility treatment center

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Other

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

Tehran University of Medical Sciences

**Full name of responsible person**

Elaheh Honarkar-Shafie

**Position**

Ph.D.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

School of Nutritional Sciences and Dietetics, No. 44, Hodjat doost Alley, Naderi St., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1416643931

**Phone**

+98 21 2296 7613

**Email**

elahehhonarkar@yahoo.com

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Elaheh Honarkar-Shafie

**Position**

Ph.D.

**Latest degree**

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elahehhonarkar@yahoo.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Elaheh Honarkar-Shafie

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### **Email**

elahehhonarkar@yahoo.com

## **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