

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

Street address

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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

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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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elahehonorakar@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

Position

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Email

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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