

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluating the effects of Iranian traditional medicine diets on erectile function and semen analysis of men

#### Protocol summary

2022-04-13, 1401/01/24

#### Study aim

Evaluating the effects of Iranian traditional medicine diets on erectile function and semen analysis of men

#### Design

A controlled clinical trial, with parallel groups, not blinded, randomised, phase 2 on 159 patient. That use Excel application for randomization.

#### Settings and conduct

Sampling will be performed on all oligospermia patients referred to the infertility clinic of clinics affiliated to Shiraz University of Medical Sciences who have consciously participated in the project after expressing the call and giving the necessary explanations.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults men with age of 18-45 years old, Oligospermia with BMI 18.5-30, Satisfaction form  
Exclusion criteria: Anatomical infertility findings, Heart and vessels diseases, Prostate cancer, Diabetes mellitus, Hypertension

#### Intervention groups

First group will receive Persian medicine regimen advices  
Second group will receive Mediterranean regimen advices

#### Main outcome variables

Oligospermia; Sexual function; Semen analysis parameters; Sexual desire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210228050534N1**

Registration date: **2022-04-13, 1401/01/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-13, 1401/01/24**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Ali Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3632 2878

##### Email address

alighasemi20@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2022-01-10, 1400/10/20

#### Expected recruitment end date

2023-01-10, 1401/10/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluating the effects of Iranian traditional medicine diets on erectile function and semen analysis of men

#### Public title

Evaluating the effects of Iranian traditional medicine diets on erectile function

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Oligospermia Iranian nation Age 18-45 Consensus Adults men BMI 18.5-30

##### Exclusion criteria:

Anatomical infertility findings Prostate cancer Heart disease Hypertension Diabetes mellitus Herbal remedies use

## Age

From **18 years** old to **45 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **159**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomisation by lottery; Researchers and volunteers can't predict the type of intervention in this study. We use the Hat App for this method. Such, numbers of all volunteers send to the Hat App. This app do lottery and a number will separate. Outcome of first lottery will entrance to Control group. Outcome of second lottery will entrance to the group that receive Iranian traditional medicine diet and outcome of third lottery will entrance to group that receive Mediterranean diet and then this method will continue till 159 volunteers do the lottery.

## 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

Ethics committee of Shiraz University of Medical Sciences

##### Street address

South Iman blvd, Sheikhi avenue

##### City

Shiraz

##### Province

Fars

##### Postal code

7185999349

#### Approval date

2021-05-12, 1400/02/22

#### Ethics committee reference number

IR.SUMS.MED.REC.1400.100

## Health conditions studied

### 1

#### Description of health condition studied

Erectile dysfunction

#### ICD-10 code

N52

#### ICD-10 code description

Male erectile dysfunction

### 2

#### Description of health condition studied

Oligospermia

#### ICD-10 code

N46.1

#### ICD-10 code description

Oligospermia

## Primary outcomes

### 1

#### Description

Semen parameters

#### Timepoint

Semen analysis in the beginning of the research, finished the first and second month after the use of diet advice

#### Method of measurement

Semen analysis

### 2

#### Description

Erectile function

#### Timepoint

Erectile function changing in the beginning of the research, finished the first and second month after the use of diet advice

#### Method of measurement

The international index of erectile function (IIEF)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: (first day) patients must fill the Iranian traditional medicine questionnaire. Rate of interest and following of the Iranian traditional medicine diet will register by scoring system of this questionnaire. So Mezaj evaluating questionnaire filled by the patient. The international sexual function questionnaire filled by this group and conclusions will calculate. Then Iranian traditional medicine diet advice by the questionnaire offered to the patients till the calculate the rate of adherence. So call to patient done every 2

weeks for calculate rate of adherency. (Day 31) , Iranian traditional medicine questionnaire and international sexual function questionnaire filled by the patients then samen analysis was done again.(Day 60) , Iranian traditional medicine questionnaire and international sexual function questionnaire filled by the patients then samen analysis was done again.

### Category

Treatment - Drugs

## 2

### Description

Second intervention group: (first day), patients must fill the Mediterranean questionnaire. Rate of interest and fallowing of the Mediterranean diet will register by scoring system of this questionnaire.So Mezaj evaluating questionnaire filled by the patient.The international sexual function questionnaire filled by this group and conclusions will calculate.Then Mediterranean diet advice by the questionnaire offered to the patients till the calculate the rate of adherency. So call to patient done every 2 weeks for calculate rate of adherency.(Day 31) , Mediterranean diet questionnaire and international sexual function questionnaire filled by the patients then samen analysis was done again. (Day 60) , Mediterranean diet questionnaire and international sexual function questionnaire filled by the patients then samen analysis was done again.

### Category

Treatment - Drugs

## 3

### Description

Control group: At this group, patients must fill the Mezaj evaluating questionnaire.The international sexual function questionnaire filled by this group and conclusions will calculate. So call to patient done every 2 weeks for calculate rate of adherency. At the beginnig of the second month ,international sexual function questionnaire filled by the patients then samen analysis was done again.At the beginnig of the third month ,international sexual function questionnaire filled by the patients then samen analysis was done again.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Faqihi hospital

##### Full name of responsible person

Abdolreza Haghpanah

##### Street address

Karim Khan Zand blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3232 6645

##### Email

faghihisp@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Rezaian Zade,Abbas,MD

##### Street address

Karim Khan Zand Blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3235 7282

##### Email

rezaiana@sums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Amir Mohammad Jaladat

##### Position

consultant

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Karim Khan Zand Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3234 5145

**Email**

drjaladat@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Amir Mohammad Jaladat

**Position**

consultant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Karim Khan Zand Blvd

**City**

Shirza

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3234 5145

**Email**

Drjaladat@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Ghasemi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

South Iman, Sheikhi avenue

**City**

Shiraz

**Province**

Fars

**Postal code**

7185999349

**Phone**

+98 71 3632 2878

**Email**

alighasemi20@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**

The participant datas withouts personal information will report

**When the data will become available and for how long**

6 month after sucesss print

**To whom data/document is available**

These datas are availabale for academic researchers

**Under which criteria data/document could be used**

For academic research

**From where data/document is obtainable**

1-Shiraz university of medical sciences, Persian medicine college,related office,call to Dr.Ghasemi Ali 2- Call to +989366545445 Dr.Ghasemi Ali 3- Email to Alighasemi20@gmail.com

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

Take a request to alighasemi20@gmail.com and after identification of the asker, data will reported

**Comments**