Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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 wil recive Persian medicine regim advices Second group will receive Mediterranean regim 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
2022-04-13, 1401/01/24

Registrant information
Name
Ali Ghasemi
Name of organization / entity
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Iran (Islamic Republic of)
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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 recive Iranian traditional medicine diet and outcome of third lottery will entrance to group that recive 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,finshed 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,finshed 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 fallowing 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 adherency. 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

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Karim Khan Zand blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Rezaian Zade,Abbas,MD

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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

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Person responsible for scientific inquiries

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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 sucsess 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