

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of Ceratonia siliqua fruit syrup and vitamin E on sperm parameters, oxidative stress index and sex hormones in infertile men.

Protocol summary

Study aim

Comparison the effect of Ceratonia siliqua fruit extract and vitamin E on sperm parameters, oxidative stress index and sex hormones in infertile men

Design

This is a parallel, single blind, randomized controlled trial and no stratification will be used.

Settings and conduct

This study will be conducted at Fateme zahra infertility and reproductive health Center affiliated to Babol university of medical sciences and take place at urology clinic. This center is one of the best-equipped diagnostic and therapeutic infertility centers and is a referral center for infertility problems in north of Iran.

Participants/Inclusion and exclusion criteria

The marital males with infertility complaints were admitted to the Urology Clinic of Fatemeh Zahra Infertility Center who have disorder in sperm concentration, motility or morphology in their spermatogenesis tests after confirmation of urologist and by having inclusion criteria and Satisfaction is entered into the study

Intervention groups

Patients will be assigned to receive carob extract twice a day or vitamin E (comparison group) 100 mg once a day for 3 months.

Main outcome variables

Primary outcome is changes in sperm parameters after treatment Secondary outcomes are changes in serum levels of reproductive hormones; Malondialdehyde (MDH) and Total antioxidant capacity (TAC), superoxide dismutase enzyme, the levels of Zinc and Selenium.

General information

Reason for update

Secondary analysis of data

Acronym

IRCT registration information

IRCT registration number: **IRCT20171209037794N1**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **prospective**

Last update: **2020-09-12, 1399/06/22**

Update count: **1**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Parvaneh Mirabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 7958

Email address

parvaneh_mirabi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Ceratonia siliqua fruit syrup and

vitamin E on sperm parameters, oxidative stress index and sex hormones in infertile men.

Public title

Effect of Ceratonia siliqua on male infertility.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20 - 45 years of age, who had complained of infertility for at least 12 months, and had no history of surgical or medical treatments for infertility Unspecified oligospermia based on WHO criteria (sperm count less than 20 million per ml, type A motility less than 25%, and type B motility less than 50%; normal morphology less than 15%); Having a BMI less than 30 Not smoking, drinking alcohol, and addiction to substance Normal level of gonadotropins, testosterone and Prolactin Lack of systemic diseases, such as diabetes and thyroid, cerebrovascular disease and had no history of chemotherapy

Exclusion criteria:

A history of vasectomy or obstructive azoospermia Azospermia and chromosomal abnormalities such as klinefelter's Syndrome Hypogonadism or pituitary abnormalities The use of antioxidant supplements in the last three months Taking medications that stimulate the sexual system or disrupt the sex hormones Having severe physical activity Genital tract infection, recurrent or residual varicocele and history of cryptorchidism Infectious diseases characterized by fever and leukocytosis.

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization will be used to achieve balance in the allocation of participants to intervention arms. Before initiation of the run- in phase of the study, two 40- sets of random numbers will be created by a member of the research team not involved in recruitment. 15 blocks with size of 4 and combination of A for the carob and B for vitamin E group will be prepared. Allocation sequence will be password-protected and only accessible to the reproductive health researcher. She folds the paper containing 4-size blocks, put them in the standard thick envelopes and write the serial numbers on them. All of the envelope will be kept at the recruitment center. Thus, for every eligible patient, the researcher randomly selects one of the

envelopes after assign subjects into intervention and comparison group.

Blinding (investigator's opinion)

Single blinded

Blinding description

outcome assessor and data analyser will be blinded to group assignment for the exploratory outcomes of treatment, treatment completion and treatment response which will be assessed by medical staff not otherwise involved in the study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

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Mazandaran, Babol, Ganj Afrooz Avenue, Babol University of Medical Sciences

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Babol

Province

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Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2018-01-24, 1396/11/04

Ethics committee reference number

MUBABOL.HRI.REC.1396.179

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

Primary outcomes

1

Description

Sperm count

Timepoint

Before and three months after intervention

Method of measurement

Semen analysis

2

Description

Sperm morphology

Timepoint

Before intervention and three months after intervention

Method of measurement

Semen analysis

3

Description

Sperm motility

Timepoint

Before and three months after intervention

Method of measurement

Semen analysis

Secondary outcomes

1

Description

Serum concentrations of Malondialdehyde

Timepoint

Before and three months after intervention

Method of measurement

TBARS method using Spectrophotometer

2

Description

Sex hormones

Timepoint

Before and three months after intervention

Method of measurement

Eliza

3

Description

superoxide dismutase enzyme

Timepoint

Before and three months after intervention

Method of measurement

Calorimetric

4

Description

Zinc

Timepoint

Before and three months after intervention

Method of measurement

Atomic Absorption Spectrophotometry

5

Description

Selenium

Timepoint

Before and three months after intervention

Method of measurement

Atomic Absorption Spectrophotometry

Intervention groups

1

Description

Intervention group: Ceratonia siliqua syrup twice a day for three months

Category

Treatment - Drugs

2

Description

Control group: 100 mg capsule of vitamin E once a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemezahra infertility center

Full name of responsible person

Dr Parvaneh Mirabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Reza Ghadimi

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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
Babol 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

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Yes
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Proportion provided by this source
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Domestic or foreign origin
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Category of foreign source of funding
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Country of origin
Type of organization providing the funding
Academic

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Domestic or foreign origin
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Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Dr Parvaneh Mirabi
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable