

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Ceratonia siliqua fruit oral capsule and vitamin E on semen parameters in idiopathic infertile men

Protocol summary

Summary

This triple-blind randomized controlled clinical trial aimed to compare the effect of ceratonia siliqua fruit oral capsule and vitamin E, on the semen parameters in infertile men. The target population of infertile men referring to infertility clinic of Al-Zahra hospital in Tabriz, which for at least one year of infertility is going on and no cause of male infertility has been established. Inclusion criteria: 20-45 years, abnormal spermogram, non-smoking and no addiction. Exclusion criteria: Being azospermic, anatomical abnormalities and infection of genital tract, taking any other chemical, or certain herbal infertility drugs and vitamin E. From seventy of infertile men, 35 men will receive ceratonia siliqua capsules and 35 men will receive vitamin E capsules for three months. The primary outcome of the study was to determine the parameters of number, motility and morphology of sperm.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041027311N1**

Registration date: **2017-02-14, 1395/11/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-14, 1395/11/26

Registrant information

Name

Behnaz Sadeghzadeh Oskouei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Ceratonia siliqua fruit oral capsule and vitamin E on semen parameters in idiopathic infertile men

Public title

Comparison of the effect of Ceratonia siliqua fruit oral capsule and vitamin E in male infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-45 years; married infertile man for at least one year with idiopathic abnormal spermogram about number; motility and morphology according to the World Health Organization (sperm count Less than 20 million per milliliter, type A mobility less than 25 percent and type B mobility less than 50% and normal morphology less than 30%); non-smoking and non-alcoholism and drug users; desire to participate in the study; the ability to read and write Exclusion criteria:

Being azospermic; infection and anatomical abnormalities of the genital tract such as duct blockage; to develop a varicocele ; surgery or need to do pelvic region surgery; diseases as cancer, liver and gallbladder, diabetes, thyroid, kidney failure, uncontrolled hypertension, cerebral hemorrhage, retinal hemorrhage, unilateral testicular atrophy; history of chemotherapy drugs, corticosteroids, anticoagulation, testosterone, antiandrogen; taking any other chemical, or certain herbal infertility drugs during the project and in the last quarter; recent consumption of vitamin E

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple 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 Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

118-51665

Approval date

2017-01-28, 1395/11/09

Ethics committee reference number

IR.TBZMED.REC.1395.1130

Health conditions studied**1****Description of health condition studied**

male infertility

ICD-10 code

N46

ICD-10 code description

male infertility

Primary outcomes**1****Description**

sperm count

Timepoint

Before and three months after intervention

Method of measurement

Semen analysis

2**Description**

sperm motility

Timepoint

Before and three months after intervention

Method of measurement

Semen analysis

3**Description**

sperm morphology

Timepoint

Before and three months after intervention

Method of measurement

Semen analysis

Secondary outcomes**1****Description**

sexual function

Timepoint

Before and three months after intervention

Method of measurement

Sexual Function Questionnaire

2**Description**

Side events

Timepoint

three months after intervention

Method of measurement

check list complete

3**Description**

Satisfaction with treatment received

Timepoint

three months after intervention

Method of measurement

check list complete

Intervention groups

1

Description

Intervention Group: 500 mg carob fruit Oral Capsules
three times a day for 90 days

Category

Treatment - Drugs

2

Description

Control group: oral 500 mg vitamin E capsules containing
100 mg of vitamin E and 400 mg starch

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Sima Sanagoo

Street address

Baghshmal Crossroads

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical
Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

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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

Research Deputy of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sima Sanagoo

Position

Student of Master of Sciences in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty