

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Carob (*Ceratonia Siliqua L*) and Ginseng supplementation versus placebo on spermogram parameters and sexual function in infertile men: a double-blind randomized clinical trial

Protocol summary

Study aim

To compare the effect of Carob (*Ceratonia Siliqua L*) and Ginseng supplementation versus placebo on spermogram parameters and sexual function in infertile men

Design

This is a double-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible infertile men who will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years Primary infertile men Abnormality of at least one parameter of semen Body mass index less than 30 Exclusion criteria: Chromosomal abnormalities, testicular insufficiency, varicocele, cryptorchidism Chronic diseases Using drug or alcohol Using medications that disrupt spermatogenesis Use of pituitary suppressants or anti-androgen Taking drugs result in ejaculation failure Taking drugs result in erection dysfunction Taking drugs such as anabolic steroids, cannabis, heroin or cocaine History of surgical procedures on the testes Contact with pesticides, heavy metals, and solvents Use of antioxidant supplements in the last three months Intense physical activity Having a slimming diet

Intervention groups

Intervention group 1: Capsule 500 mg including Carob (*Ceratonia Siliqua L*) three times a day for 12 weeks
Intervention group 2: Capsule 500 mg including Ginseng three times a day for 12 weeks
Control group: Capsule

500 mg including lactose (placebo) three times a day for 12 weeks

Main outcome variables

Primary outcome: Assessing the spermogram parameters
Assessing sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N284**

Registration date: **2019-06-13, 1398/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

Registration date

2019-06-13, 1398/03/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Carob (*Ceratonia Siliqua* L) and Ginseng supplementation versus placebo on spermogram parameters and sexual function in infertile men: a double-blind randomized clinical trial

Public title

Comparison of the effect of Carob (*Ceratonia Siliqua* L) and Ginseng supplementation versus placebo on spermogram parameters and sexual function in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 40 years Primary infertile men Abnormality of at least one parameter of semen Body mass index less than 30

Exclusion criteria:

Chromosomal abnormalities, testicular insufficiency, varicocele, cryptorchidism Chronic diseases such as diabetes, kidney disease, infectious diseases, genital tract infection, or thyroid dysfunction Using drug or alcohol Using medications that disrupt spermatogenesis (methotrexate, nitrofurantoin, colchicine and chemotherapy) Use of pituitary suppressants (testosterone, GnRh analogues) or anti-androgens (cimetidine, spironolactone) Taking drugs result in ejaculation failure (alpha-blockers, antidepressants, phenothiazide) Taking drugs result in erection dysfunction (beta-blockers, thiazide diuretics, metoclopramides) Taking drugs such as anabolic steroids, cannabis, heroin or cocaine History of surgical procedures on the testes Contact with pesticides, heavy metals and solvents Use of antioxidant supplements in the last three months Intense physical activity Having a slimming diet

AgeFrom **18 years** old to **40 years** old**Gender**

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare nine sheets of paper, writing on three sheets the name of the intervention 1 and on three other sheets the name of the intervention 2 and on the third three sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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6517838695

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.UMSHA.REC.1398.155

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

Assessing the spermogram parameters

Timepoint

12 weeks after the intervention

Method of measurement

By laboratory test

2

Description

Assessing sexual function

Timepoint

12 weeks after the intervention

Method of measurement

By history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Capsule 500 mg including Carob (Ceratonia Siliqua L) three times a day for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Capsule 500 mg including Ginseng three times a day for 12 weeks

Category

Treatment - Drugs

3

Description

Control group: Capsule 500 mg including lactose (placebo) three times a day for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan City

Full name of responsible person

Dr Seyedeh Zahra Masoumi

Street address

Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Seyedeh Zahra Masoumi

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

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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