Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
Age
From **18 years** old to **40 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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 thre 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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Hamadan
Postal code
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
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Sponsors / Funding sources

1

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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
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Dr Seyedeh Zahra Masoumi
Position
Reproductive Health Specialist

Latest degree
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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