

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

the effect of resistance training period with consumption of round palm and ginger supplement on serum levels of testosterone, LH and FSH ,sperm quality and DNA damage of infertile mens with Oligoasthenoteratospermia

Protocol summary

Study aim

Comparison of the effect of a resistance training course with palm and ginger pollen supplementation on serum levels of testosterone, LH, FSH, sperm quality and DFI infertile men oligoasthenoteratospermia.

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3 on 48 patients.

Settings and conduct

This study was performed on 48 infertile men referred to Qom University Jihad Infertility Treatment Center who were divided into 6 groups: resistance training, palm pollen supplement, ginger, resistance training - palm pollen, resistance training - ginger and control. Hormones studied Before and after treatment of blood samples taken from patients using ELISA technique testosterone, LH, FSH hormones are measured and to evaluate the effect of exercise and supplements on semen quality before and after treatment, sperm analysis is performed Finally, in order to measure the effect of exercise and supplements on the DNA health of people treated in this project, SCD test before and after treatment will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile men oligoasthenoteratospermia., age 20-40 years Conditions of absence: Oligoasthenoteratospermia with sperm count less than 10 million per ml and people with underlying diseases such as cardiovascular disease, kidney disease, diabetes and severe hormonal disorders.

Intervention groups

Control group: group without supplement (placebo)
Intervention group: 1- Exercise group with palm pollen supplement 2-Exercise group with ginger supplement 3. Exercise group without supplements 4- Palm pollen supplement group 5. Ginger supplement group

Main outcome variables

Correction of hormonal disorders, correction of sperm parameters, reduction of chromatin damage.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191210045681N2**

Registration date: **2021-04-04, 1400/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-04, 1400/01/15**

Update count: **0**

Registration date

2021-04-04, 1400/01/15

Registrant information

Name

elham asa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 3987

Email address

asa@acecr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2022-07-11, 1401/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of resistance training period with consumption of round palm and ginger supplement on serum levels of testosterone, LH and FSH ,sperm quality and DNA damage of infertile mens with Oligoasthenoteratospermia

Public title

Improvement of sperm parameters in men with oligoasthenoteratospermia by resistance training with palm or ginger pollen supplementation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile men with oligoasthenoteratospermia Age between 20-40 years

Exclusion criteria:

Oligosthenoteratospermia with sperm count less than 10 million per ml People with underlying diseases such as cardiovascular disease, kidney disease, diabetes and severe hormonal disorders

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Restricted randomization method was used. In this method it is supposed to be in one Colored glass with 48 balls with numbers 1 to 48 and For each patient by chance and draw a ball with an even number or be assigned person. Patients with even number in the treatment group and with number Individuals in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The urologist is Fully Informed about the palm or ginger Medication by Plan Holder, and the Benefits and Side Effects of the Drug are Reported to the urologist. Patients who have Entered the Study with Full Consent but have no Knowledge of Control or Intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qom University

Street address

No 13, Floor 4, Nilofar unit, Bahar Building, 3 th Alley, Naja Street, Loghman Ave

City

Qom

Province

Ghoum

Postal code

3713139476

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.QOM.REC.1399.o28

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

Oligoasthenoteratospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

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

sperm parameter, chromatin integrity, hormone levels of LH, FSH, Testosterone

Timepoint

At the beginning of the study and 8 weeks after starting the supplement and doing exercise

Method of measurement

Sperm parameters by light microscopy, chromatin health by halo sperm test and hormones by ELISA test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Ginger supplement group: During the period 500 mg of ginger supplement with a dose of two daily 2: Palm pollen supplement group: Palm pollen supplement with a dose of 100 mg twice in the morning and afternoon 3: Exercise group, 4: Ginger supplement group With exercise 5: Palm pollen group with exercise

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qom University Jihad Infertility Treatment Center

Full name of responsible person

elham asa

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No 13,Floor 4, Nilofar unit,Bahar Building,3 th Alley,Naja Street,Loghman Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

leila naser poor

Street address

Shahid Karimi Blvd., Ishar Town, Shabnam St., Qom University Jihad Infertility Center

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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

Iranian academic center for education culture and

research

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

Elham Asa

Position

Embryologist

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iranian academic center for education culture and research

Full name of responsible person

Elham Asa

Position

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Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
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Position
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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