

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Effect of CO-Q 10 supplementation versus placebo on spermogram parameters and sexual function in infertile men: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of CO-Q 10 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 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible men with primary infertility who will refer to Fatemeh 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 will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years; Man with primary infertility; Abnormality in at least one of the sperm parameters; Body mass index less than 30.
Exclusion criteria: Chromosomal abnormalities; Varicocele; Cryptorchidism; Chronic diseases such as diabetes, kidney disease, infectious diseases, genital tract infection, thyroid disorder; Drug or alcohol use; Taking spermatogenic drugs; Taking pituitary suppressive drugs; Taking anti-androgens; Taking alpha-blockers, antidepressants, or phenothiazide; History of testis surgery.

Intervention groups

Intervention group: Routine infertility treatment plus Q10 coenzyme capsule (CO-Q 10) (manufactured by Nature Mid Pharmaceuticals) 30 mg daily for 12 weeks
Control group: Routine infertility treatment plus placebo capsule (manufactured by the Laboratory of School of Pharmacy, Hamadan University of Medical Sciences) once daily for 12 weeks

Main outcome variables

Primary outcome: Sperm volume; sperm count; sperm concentration; sperm motility; sperm morphology

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N322**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of CO-Q 10 supplementation versus placebo on spermogram parameters and sexual function in infertile men: a double-blind randomized clinical trial

Public title
Effect of CO-Q 10 supplementation spermogram parameters and sexual function in infertile men

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age of 18 to 40 years, Man with primary infertility, Abnormality in at least one of the sperm parameters (volume, concentration, number, motility, or morphology), Body mass index less than 30,
Exclusion criteria:
 Chromosomal abnormalities, Varicocele, Cryptorchidism, Chronic diseases such as diabetes, kidney disease, infectious diseases, genital tract infection, thyroid disorder, Drug or alcohol use, Taking spermatogenic drugs (methotrexate, nitrofurantoin, colchicine or chemotherapy), Taking pituitary suppressive drugs (testosterone, GnRh analogs), Taking anti-androgens (cimetidine or spironolactone), Taking alpha-blockers, antidepressants, or phenothiazide, History of testis surgery

Age
From **15 years** old to **40 years** old

Gender
Male

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

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 four sheets of paper, writing on two sheets the name of the intervention and on the other two 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 four sheets are drawn. The four 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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.UMSHA.REC.1398.729

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 volume

Timepoint

Before and 12 weeks after the intervention

Method of measurement

By spermogram analysis

2

Description

Sperm count

Timepoint

Before and 12 weeks after the intervention

Method of measurement

By spermogram analysis

3

Description

Sperm concentration

Timepoint

Before and 12 weeks after the intervention

Method of measurement

By spermogram analysis

4

Description

Sperm motility

Timepoint

Before and 12 weeks after the intervention

Method of measurement

By spermogram analysis

5

Description

Sperm morphology

Timepoint

Before and 12 weeks after the intervention

Method of measurement

By spermogram analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine infertility treatment plus Q10 coenzyme capsule (CO-Q 10) (manufactured by Nature Mid Pharmaceuticals) 30 mg daily for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Routine infertility treatment plus placebo capsule (manufactured by the Laboratory of School of Pharmacy, Hamadan University of Medical Sciences) once daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Taiebeh Gharakhani

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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

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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