Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Nov 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 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 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

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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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
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
Taiebeh Gharakhani

Position
Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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