

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of Nettle and Alyssum with Q10 plus and L-Carnitine on improving sperm parameters of infertile men referred to infertility clinic

Protocol summary

Study aim

Comparison of the effect of Nettle and Alyssum with Q10 plus and L-Carnitine on improving sperm parameters of infertile men referred to infertility clinic in Jahrom city, 2021.

Design

A randomized controlled clinical trial with parallel groups, three blinded, randomized

Settings and conduct

The researcher, after approving the project in the Research Council of Rafsanjan University of Medical Sciences and obtaining the code of ethics and obtaining the necessary authorization to conduct research, will refer to the infertility clinic in Jahrom city. Male infertility are screened for entry requirements and if eligible, explaining the purpose of the study, they are invited to participate in the project and they will enter the study with written consent. To the intervention group orthidine tablets 150 mg, 3 daily and extract of Qadoomeh, 2 capsules of 300 mg daily and The control group will be given KQ10 Plus 100 mg and L-carnitine 500 mg daily For 12 weeks. T the study will be three-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study and written consent, Living with a spouse, Spouse uninfertility, Age 20 to 45 years, Disorder in at least one of the sperm parameters Infertility after 12 months of intercourse without using contraceptive methods,

Intervention groups

Intervention group: Intervention group: Taking orthidine tablets 150 mg, 3 daily and extract of Alyssum, 2 capsules of 300 mg daily and Control group: Qu10 Plus 100 mg tablets and L-carnitine 500 mg tablets daily For 12 weeks

Main outcome variables

Status of spermogram parameters, before and 12 weeks after the start of the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160308026971N12**

Registration date: **2021-07-30, 1400/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-30, 1400/05/08**

Update count: **0**

Registration date

2021-07-30, 1400/05/08

Registrant information

Name

Marzeyeh Loripoor

Name of organization / entity

Rafsanjan University Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 4950

Email address

m.loripoor@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		Blinding (investigator's opinion)	Triple blinded
Scientific title	Comparison of the effect of Nettle and Alyssum with Q10 plus and L-Carnitine on improving sperm parameters of infertile men referred to infertility clinic	Blinding description	The meaning of the three blinds is that the participants (people qualified to enter the project), Assessor (the person who is to complete the relevant checklist before and 12 weeks after treatment) And Data Analyzer (Statistics Specialist) Unaware of which group (intervention or control) the information received and statistical data belong to.
Public title	Investigating the effect of Nettle and Alyssum with Q10 plus and L-Carnitine on improving sperm parameters of infertile men	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Willingness to participate in the study and written consent Living with a spouse Iranian nationality Age 20 to 45 years Disorder in at least one of the sperm parameters (At least 20 million sperm per milliliter of semen, 50% progressive motion And 4% of normal morphology) Infertility after 12 months of intercourse without using contraceptive methods Exclusion criteria: Spouse infertility Autoimmune diseases and chronic diseases that are known to affect fertility, such as cardiovascular disease, diabetes, hypertension Alcohol, cigarette and drug addiction Mental illness Severe marital conflicts History of radiation therapy and various cancers History of previous or current genitourinary tract diseases such as varicocele	Other design features	
Age	From 20 years old to 45 years old	Secondary Ids	empty
Gender	Male	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Outcome assessor - Data analyser	Ethics committee	
Sample size	Target sample size: 70	Name of ethics committee	Ethics Committee of Rafsanjan University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	No. 33, Alley 41, Mostafa Khomeini St
Randomization description	In this study, we use a random number table to assign infertile men to the control and intervention groups. The table of random numbers consists of random digits 0 to 9 And each of the digits in this table is repeated the same on average And there is no pattern of recognizable numbers. We make a random list using the random digits in the table, assigning each digit to a therapeutic appointment. Now for the two treatments, we assign the numbers 4-0 for treatment A and the numbers 5-9 for treatment B. We start the list at an optional point in the table that we have chosen at random. For example, if we start from the top row of the random number table randomly and optionally and And from left to right of the table and then move to the bottom rows, they create a list Which begins with the following treatments. We will continue to do this until our sample is complete.	City	Rafsanjan
		Province	Kerman
		Postal code	7714668168
		Approval date	2021-06-26, 1400/04/05
		Ethics committee reference number	IR.RUMS.REC.1400.054
		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 parameters in infertile men
		Timepoint	Before the intervention and 12 weeks after the start of the intervention
		Method of measurement	

The checklist consists of two parts: the first part is the demographic characteristics and the second part is the spermogram parameters

Secondary outcomes

1

Description

Number of sperm

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

The checklist consists of two parts: the first part is the demographic characteristics and the second part is the spermogram parameters

2

Description

Sperm motility

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

The checklist consists of two parts: the first part is the demographic characteristics and the second part is the spermogram parameters

3

Description

Sperm morphology

Timepoint

Before the intervention and 12 weeks after the start of the intervention

Method of measurement

The checklist consists of two parts: the first part is the demographic characteristics and the second part is the spermogram parameters

Intervention groups

1

Description

Intervention group: Intervention group: Taking orthidine tablets (nettle) 150 mg, Made by Barij Essence Pharmaceutical Company 3 daily (7 am, 13 and 19 pm) and aqueous extract of Qadoomeh, 2 capsules of 300 mg daily (9 am and 9 pm) Which will be made by the Faculty of Pharmacy of Kerman University of Medical Sciences, For 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Control group: Qu10 Plus 100 mg tablets daily (9 am) Made by the German pharmaceutical

company Eurovital and L-carnitine 500 mg tablets daily (9 pm) Made by Karen Iran Pharmaceutical Company For 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom Infertility Clinic

Full name of responsible person

Mahnaz kargar jahromi

Street address

22 Bahman Street, in front of the governor's office

City

Jahrom

Province

Fars

Postal code

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Phone

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Email

kargarmahnaz1372@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Alo Shamsizadeh

Street address

Central Organization of Rafsanjan University of Medical Sciences and Health Services, Deputy of research and technology, Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

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Phone

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Web page address

<http://vcrt.rums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

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

Rafsanjan University of Medical Sciences

Full name of responsible person

Marzeyeh loripoor

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Nursing street

City

Rafsanjan

Province

Kerman

Postal code**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