

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Lycium barbarum polysaccharide on oxidative stress indicators and sperm health in patients with varicocele - a double-blind validated clinical trial study

Protocol summary

Study aim

Investigating the protective and antioxidant effect of (Lycium barbarum) on sperm health and function in patients with varicocele.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this clinical trial study, which will be conducted in the infertility center of Afzalipur Hospital in Kerman, 80 volunteers with type 2 varicocele were divided into two groups of 40 people, including the control group that will receive placebo and the treated group that They will receive 400 mg of polysaccharide extract (lycium barbarum) daily for two months, then after 90 days of taking the last dose, blood and semen samples will be taken to measure the serum activity of superoxide dismutase, glutathione peroxidase and malonase Dialdehyde enzymes. and testosterone hormone and sperm health parameters will be measured microscopically and macroscopically.

Participants/Inclusion and exclusion criteria

Eligibility conditions: Type 2 varicocele - Age range 18 to 65 - No varicocelelectomy Conditions for not entering the study: suffering from any secondary disease - taking any anti-inflammatory and corticosteroid drugs and strengthening drugs and supplements - occurrence and suffering from any food allergy

Intervention groups

first group: 40 patients with type 2 varicocele who receive placebo for 60 days second group: 40 patients with type 2 varicocele who receive 400 mg of Lycium barbarum polysaccharide for 60 days.

Main outcome variables

Determining the average enzyme activity of superoxide

dismutase, glutathione peroxidase, malondialdehyde, testosterone, sperm count, motility, morphology and semen volume in patients with varicocele under the administration of 400 mg Lycium barbarum polysaccharide and the control group under placebo administration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210415050978N1**

Registration date: **2023-03-18, 1401/12/27**

Registration timing: **retrospective**

Last update: **2023-03-18, 1401/12/27**

Update count: **0**

Registration date

2023-03-18, 1401/12/27

Registrant information

Name

maryam mehdikhanloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 7316

Email address

maryam.m.khanloo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-26, 1401/04/05

Expected recruitment end date

2022-07-19, 1401/04/28
Actual recruitment start date
 2022-06-26, 1401/04/05
Actual recruitment end date
 2022-07-19, 1401/04/28
Trial completion date
 2022-07-19, 1401/04/28

Scientific title
 Investigating the effect of Lycium barbarum polysaccharide on oxidative stress indicators and sperm health in patients with varicocele - a double-blind validated clinical trial study

Public title
 Investigating the effect of Lycium barbarum polysaccharide on oxidative stress indicators and sperm health in patients with varicocele - a double-blind validated clinical trial study

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having varicocele grade two
Exclusion criteria:
 No history of varicocelectomy

Age
 From **18 years** old to **65 years** old

Gender
 Male

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
 Target sample size: **80**
 Actual sample size reached: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study, we are going to collect 80 patients with type 2 varicocele and referred to the infertility center of Afzalipur Hospital in Kerman, and we will use a random number for each case, and then a different color of labels for each group. Install on the files

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study, participating patients do not know what group they are in and whether they will receive placebo or medicine. Also, the main researcher himself is not aware of this process, in line with that, the doctor and personnel participating in the project located in Afzalipur Hospital, as well as the statistical consultant and statistical analyst participating in the project have been blinded.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Rafsanjan University of Medical Sciences
Street address
 Rafsanjan university of medical science, Pesteh Blvd, KHalije fars Blvd, City: Rafsanjan
City
 Rafsanjan
Province
 Kerman
Postal code
 37718175911

Approval date
 2022-04-13, 1401/01/24

Ethics committee reference number
 IR.RUMS.REC.1401.014

Health conditions studied

1

Description of health condition studied
 Grade 2 varicocele

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
 Percentage of people with grade two varicocele

Timepoint
 Day 0 and 90 days after receiving the last dose of the drug

Method of measurement
 Diagnosis by doctor and spermogram

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients with grade 2 varicocele receiving daily placebo for 60 days

Category

Placebo

2

Description

Intervention group: Patients with grade two varicocele, prescribed with Lycium barbarum at a daily dose of 400 mg for 60 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Afzalipur Hospital

Full name of responsible person

maryam mehdikhanloo

Street address

Afzalipur Medical Education Center, near Shahid bahonar university, Imam Khomeini Highway

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Fax

Email

maryam.m.khanloo@gmail.com

Web page address

http://ah.kmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

mohammadreza haji zadeh

Street address

Central Organization, Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

info@rums.ac.ir

Web page address

<https://rums.ac.ir/#anchor8>

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

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

maryam mehdikhanloo

Position

Master student

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

No2, Dead end Nastaran, Majid pour Ave, Vanak Sq

City

Tehran

Province

East Azarbaijan

Postal code

1993919781

Phone

+98 21 8804 7316

Email

maryam.m.khanloo@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

maryam mehdikhanloo

Position

master student

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Master

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Biochemistry

Street address

No2, Dead end Nastaran, Majid pour Ave, Vanak Sq

City
Tehran
Province
Tehran
Postal code
1993919781
Phone
+98 21 8804 7316
Email
maryam.m.khanloo@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
maryam mehdikhanloo
Position
master student
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
No2, Dead end Nastaran, Majid pour Ave, Vanak Sq
City
Tehran
Province
Tehran

Postal code
1993919781
Phone
+98 21 8804 7316
Email
maryam.mkhanloo@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the presence of personal information such as addiction, failed fertility, registration of past diseases

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

No - There is not 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

No - There is not a plan to make this available