

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Effect of Curcumin Nanomicelle on Semen Parameters, Oxidative Stress, and Reproductive Hormones in Varicocele Men

Protocol summary

Study aim

Effect of Curcumin Nanomicelle on Semen Parameters, Oxidative Stress, and Reproductive Hormones in Varicocele Men

Design

Clinical Trial with Control Group with Parallel Groups, Two-way Blind, Randomized, The Study Phase does not Apply, in this Simple Individual Randomization Study Using Software The Rendering is Done.

Settings and conduct

In the Intervention Group of Varicocele Patients Treated with the Curcumin Nanomicelle Drug 80 mg Daily for 10 Weeks were Blood and Fluid Serum Samples Semen is Taken From them After Taking the Drug. In this Study, Both Researchers and Participants became Blind and the Study Site is the Qom University Jihad Infertility Center.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infertile Men with Varicocele
Conditions of Absence: Men with (Systemic Disease or Taking Medication For Systemic Disease, History of Chemotherapy or Radiation Therapy, Treatment with Anti-Inflammatory Drugs Depression)

Intervention groups

The Intervention Group, which Received 80 mg of Curcumin Nanomicelle Daily, and the Control Group, which Received a Placebo for 10 Weeks.

Main outcome variables

Semen Parameters, Sex Hormones, Stress Oxidative Level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170923036334N3**

Registration date: **2022-05-07, 1401/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-07, 1401/02/17**

Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name

Atefeh Verdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3291 7757

Email address

verdi@acecr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Curcumin Nanomicelle on Semen Parameters, Oxidative Stress, and Reproductive Hormones in Varicocele Men

Public title

Modification of Complications in Infertile Men with Varicocele by Curcumin Nanomicels

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile Men with Varicocele

Exclusion criteria:**Age**

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this Study Simple Individual Randomization Using Software The Rendering is Done.

Blinding (investigator's opinion)

Double blinded

Blinding description

Urologist by the Project Manager about the Drug Nanocell Curcumin He was Fully Informed and Informed about the Properties and Side Effects of the Drug Placement of Patients in the Control and Treatment Group is the Responsibility of the Urologist Be Patients who have Entered the Plan with Full Consent but are Informed of the Appointment There is no Control or Treatment in the Control Group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee Mashhad University Jahad

Street address

No 13, Floor 4, Nilofar Unit, Bahar Building, 3 th Alley, Naja Street, Lohman Ave

City

Qom

Province

Ghoush

Postal code

3713133483

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.ACECR.JDM.REC.1400.082

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

Varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

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

Serum Levels of Sex Hormones

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

Eliza Kit

2**Description**

Sperm Parameters

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

Standard Clinical Analysis of Semen for Evaluation of Sperm Parameters with The Usual Laboratory Method and Light Microscope According to the Organization Criteria WHO-2010 World Health Takes Place.

3**Description**

Oxidative Stress Rate

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

ROS Positive Sperms were Evaluated Using H2DCFDA (DCFH - DA: 2', 7'-dichlorodihydrofluorescein diacetate) (Sigma Co., USA) and Analyzed by Flow Cytometry.

Secondary outcomes**1****Description**

Viability

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

Viability is Assessed by Eosin-Nigrosin Staining and Examined Using a Light Microscope.

2

Description

DNA Damage Assessment

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

Tunnel Kit

3

Description

Measurement of Sperm Mitochondrial Activity

Timepoint

Before Taking the Drug and 10 Weeks After Taking the Drug

Method of measurement

Rhodamine Staining is Used to Assess the Mitochondrial Activity of Sperm.

Intervention groups

1

Description

Intervention Group: In the Intervention Group of Varicocele Patients Who were Treated with Nano-micelles Curcumin 80 mg Daily for 10 Weeks, Serum and Semen Samples were Taken from them After Taking the Drug.

Category

Treatment - Drugs

2

Description

Control group: In the Control Group of Varicocele Patients who Received Placebo for 10 Weeks, Blood Serum and Semen Samples were Taken After Taking the Drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom University Jihad Infertility Treatment Center

Full name of responsible person

Rahil Janati Far

Street address

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

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Province

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Postal code

3713133483

Phone

+98 25 3270 0155

Email

rahiljanati2016@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Leila Naser Pour

Street address

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

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Email

leilanasery@gmail.com

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

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

Iranian academic center for education culture and research

Full name of responsible person

Atefeh Verdi

Position

Embryologist

Latest degree

Ph.D.

Other areas of specialty/work

Others

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

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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

Atefeh Verdi

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Latest degree

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Other areas of specialty/work

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Email

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Its Release Schedule is not Yet Known.

When the data will become available and for how long

6 Months After Printing the Results.

To whom data/document is available

Researchers Working in Academic and Scientific Institutions.

Under which criteria data/document could be used

Provide Detailed Information to the Urologist for Treatment Infertility and Patient Well-being.

From where data/document is obtainable

Rahil Janati Far-09120510629-rahiljanati2016@gmail.com

What processes are involved for a request to access data/document

Access Data By Reading the Article.

Comments