

# 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

##### **City**

Qom

##### **Province**

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3713133483

##### **Phone**

+98 25 3270 0155

##### **Email**

## **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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##### **Phone**

+98 25 3270 0155

##### **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

##### **Street address**

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Atefeh.Verdi@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Rahil Jannatifar

**Position**

Embryologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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**Email**

rahiljanati2016@gmail.com

## 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

**Position**

Embryologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

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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**