

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation The Efficacy Of Probiotic Supplement On Sperm Parameters, Sex Hormones, Oxidative Stress Index and Inflammatory Factors In Men With Idiopathic Infertility: Randomized Double Blind Clinical Trial

#### Protocol summary

##### Study aim

The determination of the volume of ejaculation, the number of live sperm, the total sperm count, the sperm concentration, the percentage of sperm motility, the sperm count with normal morphology in the cement fluid, and the inflammatory factors including: C reactive protein (CRP) and alpha-Tumor necrosis factor (TNF $\alpha$ ) and Antioxidant factors including total antioxidant capacity (TAC) and malondialdehyde (MDA) concentration in plasma and seminal fluid and sex hormones including: testosterone, luteinizing hormone (LH), follicle stimulating hormone (FSH) and prolactin hormone

##### Design

In this study 50 idiopathic infertile men who are eligible for inclusion in the study and referred to the Urology Department of Imam Khomeini Hospital of Ahwaz Jundishapur University of Medical Sciences, Ahwaz, Iran for the treatment of infertility are selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code.

##### Settings and conduct

This study is a randomized double blind clinical trial. Idiopathic infertile men who are referred to the Urology Department of Imam Khomeini Hospital in Ahwaz, Jundishapur University of Medical Sciences, are enrolled in by the Urology Specialist. Then, 50 patients were selected and randomly divided into intervention and control groups. In this study, the investigator and the patient will be blinded to drugs and placebo.

##### Participants/Inclusion and exclusion criteria

Men with idiopathic infertility

##### Intervention groups

Intervention group: the group receiving probiotic (500 mg daily) Control group: placebo group

##### Main outcome variables

Sperm parameters, inflammatory factors, oxidative

stress indices and sex hormones

#### General information

##### Reason for update

The sleep quality questionnaire was filled out for participants but was not recorded at the time of registration on the IRCT site due to negligence.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141025019669N7**  
Registration date: **2018-01-26, 1396/11/06**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **1**

##### Registration date

2018-01-26, 1396/11/06

##### Registrant information

##### Name

Hossein Khadem Haghghian

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3375 2135

##### Email address

khadem.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation The Efficacy Of Probiotic Supplement On Sperm Parameters, Sex Hormones, Oxidative Stress Index and Inflammatory Factors In Men With Idiopathic Infertility: Randomized Double Blind Clinical Trial

**Public title**

Probiotic supplementation in infertile men

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willing to participate in the study No conception after 12 months intercourse without any contraception) Idiopathic asthenospermia according to World Health Organization criteria Normal levels of gonadotropins, testosterone and prolactin of serum

**Exclusion criteria:**

Any infection in genitourinary (GU) tract Any anatomical abnormality in GU tract Contact with pesticides, heavy metals and solvents Consumption of antioxidant supplements during last 3 months

**Age**

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are randomly divided into two groups, intervention and control groups, using randomized distribution method. In this study, the patient and researcher are blinded to medicine and placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Ahvaz Jondishapur University Of Medical Sciences

**Street address**

Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2017-11-21, 1396/08/30

**Ethics committee reference number**

IR.AJUMS.REC.1396.621

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

Asthenospermia

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

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

Sperm parameters

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram

**2****Description**

Inflammatory factors

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**3****Description**

Antioxidant indices

**Timepoint**

Before intervention and after intervention

**Method of measurement**

Eliza

#### 4

**Description**

Sex hormones

**Timepoint**

Before intervention and after intervention

**Method of measurement**

Eliza

#### 5

**Description**

Sleep quality

**Timepoint**

Before intervention and after intervention

**Method of measurement**

Petersburg's sleep quality questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group: Probiotic, 500 mg per daily

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: Placebo

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Urology Clinic, Imam Khomeini Hospital, Ahvaz  
Jondishapur University of Medical Sciences

**Full name of responsible person**

Dr. Bizhan Helli

**Street address**

Jondishapur University Of Medical Sciences, Golestan  
Ave. Ahvaz

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+98 61 1373 8254

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bizhanhelli@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Bizhan Helli

**Street address**

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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Bizhan Helli

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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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)**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data on primary and secondary outcomes will be published.

**When the data will become available and for how long**

After completing the study and analyzing the data

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

There is no objection to the use of data provided the source of the resource.

**From where data/document is obtainable**

IRCT site

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

Six months after the study

**Comments**