

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 α) 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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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