Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of probiotic and antioxidant use on the improvement of semen parameters in men with primary idiopathic infertility: a randomized clinical trial

Protocol summary

Study aim

Determining the use of probiotics and antioxidants on improving semen parameters in men with primary idiopathic infertility

Design

This study is a randomized, three-blind, phase 3 clinical trial performed on 102 patients. Patients are randomly divided into 3 groups of 34 by random allocation software and one group is taking probiotic and one group is taking anti oxidant and the other group is taking a placebo.

Settings and conduct

This study is performed in Yazd Infertility Center and Isfahan Urology Clinic. Patients with primary idiopathic infertility are divided into three groups: a probiotic group, an antioxidant group, and a placebo group. Sperm samples are taken for analysis before the study and 3 months after the study. This study is three-way blind and the patient, caregiver and analyzer do not know the study group.

Participants/Inclusion and exclusion criteria

The condition for admission is men with primary idiopathic infertility, and the conditions for not entering and leaving the study are: 1- Pyospermia 2- History of testicular surgery 3. History of chemotherapy or radiotherapy 4. Smoking 5 - History and current use of drugs affecting spermatogenesis such as tamoxifen, hcg, cytotoxic drugs such as immunosuppressants, anticonvulsants, androgens 6. History of sexually transmitted diseases 7- Epididymarkit 8- Testicular trauma 9-Prostatitis 10- Reluctance to participate in the study 11- Chromosomal abnormalities 12- Pregnancy event during the study 13- History of testicular torsion

Intervention groups

In this study, a probiotic group, an antioxidant group, and a placebo group were given.

Main outcome variables

1-Semen volume 2-Sperm count 3-Sperm concentration 4-Sperm motility 5-Sperm morphology 6-DNA fragmentation index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150420021869N5**
Registration date: **2021-10-14, 1400/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-14, 1400/07/22**
Update count: **0**

Registration date

2021-10-14, 1400/07/22

Registrant information

Name
Farshad Gholipour
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of probiotic and antioxidant use on the improvement of semen parameters in men with primary idiopathic infertility: a randomized clinical trial

Public title

The effect of probiotic and antioxidant use on the semen parameters

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men with primary idiopathic infertility Age 18 to 45 years

Exclusion criteria:

Pyospermia History of testicular surgery History of chemotherapy or radiotherapy smoking History and current use of drugs that affect spermatogenesis such as tamoxifen, hcg, cytotoxic drugs such as immunosuppressants, anticonvulsants, androgens History of sexually transmitted diseases Epididymitis and orchitis Testicular trauma Prostatitis Reluctance to participate in the study Chromosomal abnormalities Pregnancy event during the study History of testicular torsion

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly assigned to 3 control and intervention groups (probiotics, antioxidants, and placebo) by random allocation software in individual units. Block randomization will be used with a block size of 6. Sealed envelopes containing a number attributed to each intervention group will be used. The patient and the practitioner are blinded to the intervention received.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a triple blind study in which the participants and the clinical caregiver and the analyzer are blind and patient group are selected by random allocation software. Randomly assigned to the case or control group (probiotics, antioxidants, and placebo). Then, if he is in any group, he will receive a drug that is appropriate for the group, and all three drugs are similar in shape. But patients and caregivers do not know which medication or placebo they received, and outcome assessors do not know the participants and record their findings based on patient numbers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.MUI.MED.REC.1400.443

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

seminal fluid volume

Timepoint

before intervention and 3 months after intervention

Method of measurement

semen analysis

2

Description

sperm count

Timepoint
before intervention and 3 months after intervention
Method of measurement
semen analysis

3

Description
sperm concentration
Timepoint
before intervention and 3 months after intervention
Method of measurement
semen analysis

4

Description
sperm motility
Timepoint
before intervention and 3 months after intervention
Method of measurement
semen analysis

5

Description
sperm morphology
Timepoint
before intervention and 3 months after intervention
Method of measurement
semen analysis

6

Description
DNA Fragmentation Index
Timepoint
before intervention and 3 months after intervention
Method of measurement
semen analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In this group, patients receive one Familact capsule containing 500 mg of synbiotics made by Zist takhmir Pharmaceutical Company for 3 months
Category
Treatment - Drugs

2

Description
Intervention group: In this group, they receive one sperigen capsule containing antioxidants made by Hayat Daru Iran Company daily for 3 months.
Category
Treatment - Drugs

3

Description
Control group: In this group, patients receive one capsule daily similar to the intervention group without effective substance for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Center
Full name of responsible person
Amirhosein Rahavian
Street address
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjooy Javanmard
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Web page 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
Esfahan University of Medical Sciences

Proportion provided by this source
50

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
Esfahan University of Medical Sciences
Full name of responsible person
Farshad Gholipour
Position
Assistant professor of Urology
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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)
Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available