Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of probiotic supplement on reducing oxidative stress and sperm quality in patients with asthenospermia

Protocol summary

Study aim
The effect of probiotic supplement on reducing oxidative stress and sperm quality in patients with asthenospermia

Design
This study has two phase blinds of phase 2-3. Which are selected on 20 infertile men with asthenospermia who meet the inclusion criteria and refer to the infertility ward of Kashan Beheshti Hospital for infertility treatment. Participants are randomly divided into intervention and control groups by random allocation software with parallel groups.

Settings and conduct
The present study is a double-blind randomized clinical trial. Infertile men with asthenospermia who go to the infertility center of Beheshti Hospital in Kashan for treatment are studied by a urologist, the consultant of this project. Then 20 patients are selected and randomly divided into intervention and control groups. In this study, the therapist and patient will be blinded to the drug and placebo.

Participants/Inclusion and exclusion criteria
entrance: People with asthenospermia and infertility problems due to abnormal sperm motility Exit: People outside the age group and using a special drug to treat infertility and other diseases, people on a diet rich in probiotics

Intervention groups
Intervention group: FAMILACT probiotic receiving group with 109 CFU dose Control group: placebo receiving group

Main outcome variables
Sperm and fluid parameters of semen, oxidative stress index of malondialdehyde (MDA) measurement of semen, measurement of sperm chromatin structure (DFI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220119053769N1**
Registration date: **2022-01-28, 1400/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-28, 1400/11/08**
Update count: **0**

Registration date
2022-01-28, 1400/11/08

Registrant information

Name
Mina Toghraei Semiromi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5366 3610

Email address
toghraei-m@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-11, 1400/06/20

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotic supplement on reducing oxidative stress and sperm quality in patients with asthenospermia

Public title

The effect of probiotic supplement on reducing oxidative stress and sperm quality in patients with asthenospermia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with asthenospermia and infertility problems due to abnormal sperm motility

Exclusion criteria:

People outside the age group of 18-40 People who take certain medications to treat infertility People on a diet rich in probiotics People with asthenospermia who are forced to take certain medications during the illness

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Before intervention and after intervention

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants are randomly divided into two groups of control and intervention by random allocation software in individual units. Then, the number of each patient is given to the software and the patient group, ie intervention or control, is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study has two aspects of blindness in which participants and evaluators of blind outcome. And randomization is done by random allocation software. Participants are randomly divided into intervention or control groups by random allocation software. Then, if they are in the intervention group, they will receive medicine, and if they are in the control group, they will receive a placebo, which is quite similar to medicine. But patients do not know whether they are receiving medication or not. Outcome assessors are also unaware of the group of 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

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan - 15 Khordad Square, Shahrdari St., Kashan University of Medical Sciences

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2021-08-14, 1400/05/23

Ethics committee reference number

IR.KAUMS.REC.1400.029

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 and semen parameters

Timepoint

Before the intervention and after the intervention

Method of measurement

Spermatogram

Secondary outcomes

1

Description

Measurement of malondialdehyde (MDA) semen

Timepoint

Before intervention and after intervention

Method of measurement

Eliza

2

Description

DNA fragmentation index test

Timepoint

Before intervention and after intervention

Method of measurement
Using Acidic Aniline Blue staining

Intervention groups

1

Description
Intervention group: FAMILACT probiotic with a dose of 109 CFU
Category
Treatment - Drugs

2

Description
Control group: Plasbo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Beheshti Hospital of Kashan
Full name of responsible person
Dr. Ghazaleh Meshkdanian
Street address
Kashan - 15 Khordad Square, Shahrdari Street
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5544 3022
Email
g_moshkdanian@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Meshkdanian
Street address
Kashan - 15 Khordad Square, Shahrdari Street
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5544 3022
Email
g_moshkdanian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Meshkdanian
Position
science Committee
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
Street address
Kashan - 15 Khordad Square, Shahrdari Street
City
Kashan
Province
Isfehan
Postal code
8715973474
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Phone
+98 31 5544 3022
Email
g_moshkdanian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Ghazaleh Meshkdanian
Position
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Kashan - 15 Khordad Square, Shahrdari Street
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5366 7522
Email
minatoghraei75@gmail.com

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
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
Primary and secondary outcome data will be published.
When the data will become available and for how long
After studying and analyzing the data
To whom data/document is available
All researchers
Under which criteria data/document could be used
There is nothing wrong with using data provided the source is mentioned.
From where data/document is obtainable
To the IRCT site
What processes are involved for a request to access data/document
Six months after the study
Comments