Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Assessing the effect of probiotic administration on sperm DNA fragmentation, sperm parameters and seminal oxidative stress in men diagnosed with idiopathic infertility

Protocol summary

Study aim
This study aims to assess the effect of probiotic administration on male subjects with idiopathic infertility. We intend to evaluate the effect of supplementation with FamiLact probiotic compound on our participants regarding the level of DNA damage and protamine deficiency, as well as regular sperm parameters.

Design
A triple blinded, placebo-controlled clinical trial, randomized applying permuted blocks

Settings and conduct
60 patients recruited in Imam Reza Hospital will randomly be divided into two equal placebo- and probiotic receivers groups. Applying a triple blinding strategy, the patients, care providers, researchers, and the data analyzer will be masked. Patients in the treatment and placebo groups receive 500 mg of probiotic and identical placebo for 80 days respectively. In addition to regular semen parameters, level of DNA damage and protamine deficiency in sperm will be evaluated prior to intervention and after termination of the course of supplementation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men with idiopathic male infertility
Exclusion criteria: cryptorchidism, varicocele, chromosome abnormalities, leukocytospermia, epididymo-orchitis, genito-urinary traumas, prostatitis, testicular torsion, history of inguinal/genital surgery, history of hormone therapy, endocrinopathies, history or present use of cytotoxic/immunosuppressant/anticonvulsant/androgen drugs, recent sexually transmitted infection.

Intervention groups
Drug group: receiving of 500 mg of FamiLact containing probiotic bacterial strains and 10^9 CFU of Fructooligosaccharides on a daily basis (1 capsule/day).
Control group: receiving 1 capsule of identical placebo per day.

Main outcome variables
Routine sperm parameters; sperm DNA damage; sperm protamine deficiency

General information

Reason for update
Due to termination of the trial.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190824044599N1**
Registration date: **2019-10-27, 1398/08/05**
Registration timing: **prospective**

Last update: **2021-02-27, 1399/12/09**
Update count: **1**

Registration date
2019-10-27, 1398/08/05

Registrant information

Name
Behzad Abbasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 7428

Email address
bhzd.abbasy@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
2019-11-22, 1398/09/01
Actual recruitment end date
2020-05-02, 1399/02/13
Trial completion date
2020-05-02, 1399/02/13

Scientific title
Assessing the effect of probiotic administration on sperm DNA fragmentation, sperm parameters and seminal oxidative stress in men diagnosed with idiopathic infertility

Public title
Effect of probiotic administration on male infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile men with abnormal sperm analysis due to unknown underlying cause
Exclusion criteria:
Cryptorchidism Varicocele Chromosome abnormalities Leukocytospermia Epididymo-orchitis History of trauma to genitourinary system Prostatitis History of testicular torsion Previous inguinal surgeries History of Hormonetherapy History of endocrinopathies History of medication with cytotoxic drugs, immunosuppressants, androgens, and anticonvulsants Recent sexually transmitted infection
Age
From **18 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Participants must provide us with two semen samples: before and 80 days after receiving the intervention.
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
We will recruit permutation block randomization method. Regarding our sample size, 9 blocks containing 8 units (individuals) will be applied. Random sequence will be built on all the possible permutations. Due to our triple blinded design, no allocation concealment will be used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Drug and placebo packings are identical and given to the participants according to randomization sequence. In the present study, health caregivers, researcher(s) in charge of data collection and manuscript drafting, as well as statistical analysis will be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of AJA University of Medical Sciences
Street address
AJA University of Medical Sciences, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2019-07-30, 1398/05/08
Ethics committee reference number
IR.AJAUMS.REC.1398.051

Health conditions studied

1

Description of health condition studied
Idiopathic male infertility
ICD-10 code
N46.9
ICD-10 code description
Male infertility, unspecified

Primary outcomes

1

Description
sperm concentration
Timepoint
Evaluating sperm concentration before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

2

Description
Semen volume

Timepoint
Evaluating semen volume before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

3

Description
Percentage of abnormal sperm morphology
Timepoint
Evaluating the percentage of abnormal sperm morphology before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

4

Description
Percentage of sperm motility
Timepoint
Evaluating the percentage of motile sperm before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

5

Description
Percentage of sperm progressive motility
Timepoint
Evaluating the percentage of sperm progressive motility before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

6

Description
Percentage of sperm lipid peroxidation
Timepoint
Evaluating the percentage of sperm lipid peroxidation before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

7

Description
Intensity of sperm lipid peroxidation
Timepoint
Evaluation the intensity of sperm lipid peroxidation before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

8

Description
Percentage of sperm DNA damage index
Timepoint
Evaluating the percentage of sperm DNA damage index before and 80 days after probiotic administration
Method of measurement
Semen sample analysis (SCSA test)

9

Description
Percentage of sperm protamine deficiency
Timepoint
Evaluating the percentage of sperm protamine deficiency before and 80 days after probiotic administration
Method of measurement
Semen sample analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group of patients receiving a single capsule (500 mg) of FamiLact daily (after meal). Each capsule of FamiLact contains bacterial strains of Lactobacillus rhamnosus, Lactobacillus casei, Lactobacillus bulgaricus, Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Streptococcus thermophilus and also 10^9 CFU of Fructooligosaccharides as prebiotic. FamiLact is a product of Zist Takhmir Pharmaceutical Company, under the permission of Food and Drug department of the Ministry of Health and Medical Education (reference no.: 0347756442342525).
Category
Treatment - Drugs

2

Description
Control group: A group of patients receiving a capsule containing 500 mg of starch per day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital (501 Artesh)
Full name of responsible person
Behzad Abbasi
Street address
Imam Reza Hospital, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran

Postal code
1411718541
Phone
+98 21 8609 6350
Email
bhzd.abbasy@gmail.com
Web page address
http://imamreza.ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mostafa Shahrezayi
Street address
AJA University of Medical Sciences, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8802 8350
Email
bhzd.abbasy@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Behzad Abbasi
Position
Research assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
AJA University of Medical Sciences, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
bhzd.abbasy@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Behzad Abbasi
Position
Research assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
AJA University of Medical Sciences, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
bhzd.abbasy@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Behzad Abbasi
Position
Research assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
AJA University of Medical Sciences, Etemadzadeh St., West Fatemi Ave.
City
Tehran
Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

bhzd.abbasy@gmail.com

Web page address

http://www.ajaums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Data on primary and secondary findings will be published as well as the analysis.

When the data will become available and for how long

The access will be granted 6 month after the publication

To whom data/document is available

Researchers in universities or research institutions

Under which criteria data/document could be used

Any purpose

From where data/document is obtainable

Through contacting corresponding author

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

Contacting corresponding author through E-mail

Comments