

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Efficacy of Synbiotic (FamiLact) as an Adjuvant Therapy in Improvement of Semen Parameters of Patients Undergoing Varicocelelectomy: A Randomized Double-Blinded Controlled Trial

Protocol summary

Study aim

Evaluation of semen parameters after varicocelelectomy in probiotic group and placebo group

Design

This study is a phase 3 double-blind randomized clinical trial performed on 84 patients. Patients are randomly divided into two groups of 42 by random allocation software, which intervention group receives symbiotic and the placebo control group.

Settings and conduct

This study is performed in the Baqiyatallah Hospital of Tehran. Infertile patients are divided into two groups after the varicocelelectomy and one group is taking synbiotics and the other group is taking a placebo. This is a two-sided blind study in which participants and outcome assessors are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all men with infertility who are candidates for unilateral varicocelelectomy. exclusion criteria include cryptorchidism, epididymorchitis, genitourinary trauma, prostatitis, testicular torsion, history of inguinal or genital surgery, history of hormonal therapy, endocrinopathies, history or current use of cytotoxic drugs such as immunosuppressants and immunosuppressants, Recent sexually transmitted infections.

Intervention groups

In this study, the intervention group is given a symbiotic capsule and the control group is given a capsule similar to the intervention group without effective substance.

Main outcome variables

1- seminal fluid volume 2- sperm number 3-sperm concentration 4-sperm motility 5-sperm with normal morphology 6-pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150420021869N4**

Registration date: **2021-08-06, 1400/05/15**

Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**

Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name

Farshad Gholipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Synbiotic (FamiLact) as an Adjuvant Therapy in Improvement of Semen Parameters of Patients Undergoing Varicocele: A Randomized Double-Blinded Controlled Trial

Public title

the effect of synbiotic on seminal fluid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men with infertility who are candidates for unilateral varicocele

Exclusion criteria:

Cryptorchidism Epididymitis and orchitis urogenital trauma prostatitis testicular torsion history of inguinal or genital surgery history of hormone therapy endocrinopathy history or current use of cytotoxic drugs, anti epileptic agent and androgens recent history of sexual transmitted disease

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly assigned to control and intervention groups in individual units by random allocation software. In this way, the number of each patient is given to the software and the patient group (case or control) is specified.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded study in which participants and evaluators of the outcome are blind. In such a way the participant by random allocation software is randomly assigned to the case or control group. Then, if he is in the case group, he will receive the drug, and if he is in the control group, he will receive a completely similar placebo. The participants don't know that they are receiving medication or the placebo and the outcome assessors do not know the group of participants too 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 Baqiyatallah Hospital

Street address

vanak square, mulla sadra street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.049

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 varicocele and 3 months after surgery

Method of measurement

seminal analysis

2

Description

sperm count

Timepoint

before varicocele and 3 month after varicocele

Method of measurement

seminal analysis

3

Description

sperm concentration

Timepoint

before varicocele and 3 month after

varicocelectomy
Method of measurement
seminal analysis

4

Description
progressive sperm motility
Timepoint
before varicocelectomy and 3 month after
varicocelectomy
Method of measurement
seminal analysis

5

Description
sperm with normal morphology
Timepoint
before varicocelectomy and 3 month after
varicocelectomy
Method of measurement
seminal analysis

6

Description
fertility
Timepoint
6month after varicocelectomy
Method of measurement
pregnancy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients receive one
Familact capsule containing 500 mg of synbiotics made
by Zist takhmir Pharmaceutical Company for 6 months.
Category
Treatment - Drugs

2

Description
Control group: In this group, patients receive one capsule
per day similar to the intervention group without the
effective substance for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Baqiyatallah hospital
Full name of responsible person
Farshad Gholipour
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Vanak square, Mollasadra street, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Gholam Hossein Alishiri
Street address
Vanak square, Mollasadra street, Tehran, Iran
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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
Bagheiat-allah 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
Esfahan University of Medical Sciences
Full name of responsible person

Farshad Gholipour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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