# 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 Varicocelectomy: A Randomized Double-Blinded Controlled Trial

## Protocol summary

**Study aim**

Evaluation of semen parameters after varicocelectomy 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 varicocelectomy 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 varicocelectomy. 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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+98 21 6636 2089

**Email address**

f-gholipour@student.tums.ac.ir

**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 Varicocelectomy: 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 varicocelectomy

**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 varicocelectomy and 3 months after surgery

**Method of measurement**
seminal analysis

### 2

**Description**
sperm count

**Timepoint**
before varicocelectomy and 3 month after varicocelectomy

**Method of measurement**
seminal analysis

### 3

**Description**
sperm concentration

**Timepoint**
before varicocelectomy 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
**Street address**
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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Hezar jarib street

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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