

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluating the effects of symbiotic therapy in male infertility with idiopathic oligoasthenospermia

#### Protocol summary

##### Study aim

Evaluation of the therapeutic effect of synbiotics in the treatment of idiopathic oligoasthenospermia in men

##### Design

Blind two-way clinical trial; patients were randomly assigned to two groups of 20 recipients of femoral lactate or placebo by blockchain and would receive their group medication once daily for 4 weeks. Therefore, on a basic basis, demographic and clinical information of registered patients, as well as a serum sample will be taken for the necessary analyzes.

##### Settings and conduct

Yazd Reproductive Research Institute

##### Participants/Inclusion and exclusion criteria

Admission requirements: Age 20 to 50 years, Sperm concentration below 15 million per cc, Percentage of progressive motile spermatozoa < 32%, Total ejaculated spermatozoa < 39\*10<sup>6</sup>, Total motility < 40%, Normal serum levels of free testosterone, Prolactin, Luteinizing hormone, Follicle-stimulating hormone, Conditions for not entering the study: Drug or alcohol abuse, Concentration of white blood cells in semen > 106 per cc, Possibility of being treated with gonadotropins, anabolic steroids, cancer chemotherapy, NSAIDs, infertility medications in the last two months, Previous history of chemotherapy or radiotherapy for cancer, Existence of palpable varicocele, X-ray history of the past eight months, Y chromosome microdeletion, Karyotype alterations, Testicular atrophy and testicular failure, Other secondary causes of infertility, A history of liver problems and a history of allergy to clomiphene, Percentage of typical forms < 4%, Ejaculated volume < 1.5 ml, Abnormal serum levels of free testosterone, Prolactin, Luteinizing hormone, Follicle-stimulating hormone

##### Intervention groups

Intervention group: They receive FamiLact capsules once a day for 4 weeks. Control group: They receive placebo once a day for 4 weeks.

##### Main outcome variables

Sperm concentration; sperm motility; sperm morphology; semen fluid volume

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190810044500N6**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **prospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

##### Registration date

2020-09-05, 1399/06/15

##### Registrant information

##### Name

Fatemeh Saghafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 3419

##### Email address

f.saghafi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effects of symbiotic therapy in male infertility with idiopathic oligoasthenospermia

**Public title**

Evaluating the effects of symbiotic therapy in male infertility with idiopathic oligoasthenospermia

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 20 to 50 years Sperm concentration below 15 million per cc Percentage of progressive motile spermatozoa < 32% Total ejaculated spermatozoa < 39\*10<sup>6</sup> Total motility < 40% Normal serum levels of free testosterone, Prolactin, Luteinizing hormone, Follicle-stimulating hormone

**Exclusion criteria:**

Drug or alcohol abuse Concentration of white blood cells in semen > 106 per cc Possibility of being treated with gonadotropins, anabolic steroids, cancer chemotherapy, NSAIDs, infertility medications in the last two months Previous history of chemotherapy or radiotherapy for cancer Existence of palpable varicocele X-ray history of the past eight months Y chromosome microdeletion Karyotype alterations Testicular atrophy and testicular failure Other secondary causes of infertility A history of liver problems and a history of allergy to clomiphene Percentage of typical forms < 4% Ejaculated volume < 1.5 ml Abnormal serum levels of free testosterone, Prolactin, Luteinizing hormone, Follicle-stimulating hormone

**Age**

From **20 years** old to **50 years** old

**Gender**

Male

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into two groups of recipients of femoral lactate or placebo capsules using Random Allocation software using reciprocating blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All stages will be covered by the patient, physician, and evaluator. The first presenter identifies the sequence of assignment of patients according to the order of entry of the patients to the study and places the drugs in a

uniform envelope and identifies them with A or B codes. He then identifies the medications that are appropriate for each individual according to the above description and puts them in special envelopes and delivers them to patients.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Faculty of ethics of medical sciences, shahid sadoughi university of medical sciences

**Street address**

Professor Hesabi Blvd, Yazd Province

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173149

**Approval date**

2020-07-07, 1399/04/17

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1399.057

**Health conditions studied****1****Description of health condition studied**

Idiopathic oligoasthenospermia

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sperm concentration in semen

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram test

**2****Description**

Sperm motility in semen

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram test

**3****Description**

Sperm morphology in Semen

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram test

**4****Description**

Semen fluid volume

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram test

**5****Description**

Semen fluid Power Hydrogen

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Spermatogram test

**6****Description**

Serum concentration of free testosterone, prolactin, luteinizing hormone, follicle-stimulating hormone

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Blood test

**Secondary outcomes****1****Description**

Age

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Questionnaire

**2****Description**

Height

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Questionnaire

**3****Description**

Weight

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Questionnaire

**Intervention groups****1****Description**

Intervention group: They receive FamiLact capsules once a day for 4 weeks.

**Category**

Treatment - Drugs

**2****Description**

Control group: They receive placebo once a day for 4 weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yazd Reproductive Sciences Research Institute

**Full name of responsible person**

Fatemeh Saghafi

**Street address**

Safaieh, Timsar Fallahi Street

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**Postal code**

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**Email**

ivf@ssu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mohamad Reza Mirjalili

**Street address**

Bahonar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

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ravabet@SSU.AC.IR

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh Saghafi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

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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