

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

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

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*10⁶, 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

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)

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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*10⁶ 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

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Professor Hesabi Blvd, Yazd Province

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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

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Safaieh, Timsar Fallahi Street

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

Yazd University of Medical Sciences

Full name of responsible person

Mohamad Reza Mirjalili

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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

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

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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