

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparing the effects of symbiotic therapy with clomiphene in male infertility with idiopathic oligoasthenospermia: a randomized clinical trial

Protocol summary

Study aim

Comparison of the therapeutic effect of synbiotic with clomiphene in the treatment of idiopathic infertility in men

Design

A randomized, double blind clinical trial with a parallel group design of 30 patients in each group (totally 60 patients), and followed for 2 months. Randomization will be done with computer.

Settings and conduct

This study will be a double-blind clinical trial in 1398-99. The study population consisted of 20-50 year old male patients referred to infertility clinics in Bojnourd city who have been infertile for one year and their diagnosis is idiopathic. Patients in the study will be randomly assigned to either a probiotic group receiving one capsule daily or clomiphene (25 mg daily). The patients will be randomly assigned to each group. Randomization will be done using a computer. For the purpose of random assignment correctly, the code of any intervention will be kept confidential by the clinic secretary, regardless of the patients' condition and in the envelopes. Then, the sealed envelopes will be delivered to treating physician to use for assigning patients to groups.

Participants/Inclusion and exclusion criteria

Including criteria: Sperm concentration in semen <15000000 per cc; Percentage of progressive motile spermatozoa < 32%; Total motility <40%; Total ejaculated spermatozoa<39*10⁶; Normal level of FSH, LH, Prolactin, and free testosterone in serum; Excluding criteria: Smoking or alcoholic consumption; White blood cells in semen >10⁶; History of infertility therapy, chemotherapy and exposing to toxic agents on gonads; Rule out of infertility with idiopathic oligoasthenospermia.

Intervention groups

Intervention group: one capsule of Familact available in Iranian Pharmaceutical Market, orally Control group: one capsule of clomiphene available in Iranian

Pharmaceutical Market, orally

Main outcome variables

Semen Liquid Sperm Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044653N3**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

Maryam Rameshrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

mrameshrad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effects of symbiotic therapy with clomiphene in male infertility with idiopathic oligoasthenospermia: a randomized clinical trial

Public title
Comparing the effects of symbiotic therapy with clomiphene in male infertility with idiopathic oligoasthenospermia: a randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
sperm concentration in semen <15000000 per cc
Percentage of progressive motile spermatozoa < 32%
Total motility <40% Total ejaculated spermatozoa<39*10⁶ Normal level of FSH, LH, Prolactin, and free testosterone in serum
Exclusion criteria:
Smoking or alcoholic consumption White blood cells in semen >10 6 Chances of being treated with gonadotropins, anabolic steroids, cancer chemotherapy, NSAIDs Have been treated with infertility medications since two months ago Unwillingness to cooperate during treatment A medical history of chemotherapy or radiotherapy for cancer management A history of X ray radiation exposure since 8 months ago Y chromosome microdeletion Karyotype alterations Testicular atrophy and lack of testicular descending Other secondary causes of infertility History of liver dysfunction and sensitivity to clomiphene Medical history of infertility therapy since 2 months ago Ejaculated volume <1.5 ml Percentage of typical forms<4% abnormal level of FSH, LH, prolactin and free testosterone in serum

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

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted Block Randomization will be used. At first, the block size is considered 4. Then, the possible ways to equally assign participants to a block will be written for 60 subjects. (AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)-BABA(5)-...- BAAB(n)). After that, numbers between 1-n will be chosen randomly from the table of random numbers which shows the ordinary of the blocks for participating in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description
Type of the interventions are kept in sealed envelopes and receive a code with no detail by the secretary. Doctors, patients and analyzer don't know the group of the patients. Two groups are nominated A or B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences
Street address
shahria streat
City
Bojnurd
Province
North Khorasan
Postal code
9417694786

Approval date
2019-11-16, 1398/08/25

Ethics committee reference number
IR.NKUMS.REC.1398.094

Health conditions studied

1

Description of health condition studied
male infertility with idiopathic oligoasthenospermia

ICD-10 code
N46

ICD-10 code description
Male infertility

Primary outcomes

1

Description
sperm concentration in semen

Timepoint
end of study

Method of measurement
Sperm count in semen is calculated using sperm concentration. Sperm concentration refers to the number of sperm per unit volume of semen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one capsule of Familact available in Iranian Pharmaceutical Market, orally

Category

Treatment - Drugs

2

Description

Control group: one capsule contain of clomiphene available in Iranian Pharmaceutical Market, orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility clinics in Bojnourd city

Full name of responsible person

Abdollah razi

Street address

Shahriar

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North Khorasan

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9417694786

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abdolahrazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

vice chancellor of research

Street address

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Abdollah Razi

Position

Assicant

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Maryam Rameshrad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahriar Street,

City

Bojnurd

Province

North Khorasan

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