

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The study of the effect of combination herbal therapy (zayesh boolidaroo® + Safoof hefz + Royal gel) on sperm quality and chromatine integrity in oligoasthenoteratozoospermia men

Protocol summary

Study aim

This study was to compare routine drugs with traditional medicine, Zayesh Majoon, Royal Jelly capsule and Safoof hefz capsule in patients with oligoasthenoteratozoospermia in the age range of 20 to 50 years.

Design

A randomized clinical trial performed on 2 groups of 20 patients with oligo asthenoteratozoospermia

Settings and conduct

To patients with oligo-stenoteratozo sperm with semen test, if there are inclusion criteria, the treatment process is explained and if the patient agrees to participate in the study, first a demographic questionnaire and consent form and then semen analysis is performed. If conditions are present, patients are randomly divided into two groups. At the end of the period, sperm analysis and other retests are performed to check for possible changes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with oligoasthenoteratozoospermia (Total sperm count is 15 or less than 15 million per milliliter. The percentage of normal morphology or appearance is less than 4. Sperm motility is less than 40%.) The patient's spouse is fertile. Have a history of infertility for at least one year. Exclusion criteria: History of receiving chemotherapy drugs, corticosteroids, anticoagulants, testosterone, anti-androgens two months before the start of the study. Genital infections, anatomical abnormalities, chromosomal abnormalities, history of genital surgery (varicocele, ...) Alcohol or drug use. Patients with ejaculatory disorders. Systemic diseases.
Cr > 1.5. Sgot > 80. Sgpt > 80. Hb < 10

Intervention groups

The first group Receiving of routine drug male Infertility (90-day period) The second group Receiving of Zayesh Majoon, Royal Jelly capsule and Safoof hefz capsule (made

by BoooliDaroo company) in a period of 90 days

Main outcome variables

Sperm count, sperm motility, sperm morphology, sperm DNA fragmentation, protamine deficiency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048878N1**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Leila Naserpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 0155

Email address

leilanasery48@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The study of the effect of combination herbal therapy (zayesh bootalidaroo®+ Safoof hefz + Royal gel) on sperm quality and chromatine integrity in oligoasthenoteratozoospermia men

Public title
Comparison of the effect of combined herbal medicine with routine medicine on sperm quality and chromatine integrity in oligoasthenoteratozoospermia men

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with oligo asthenotratospermia(Total sperm count is 15 or less than 15 million per milliliter.The percentage of normal morphology or appearance is less than 4.Sperm motility is less than 40%. The patient's spouse is fertile. Have a history of infertility for at least one year.

Exclusion criteria:

History of receiving chemotherapy drugs, corticosteroids, anticoagulants, testosterone, anti-androgens two months before the start of the study Genital infections, anatomical abnormalities, chromosomal abnormalities, history of genital surgery (varicocele, ...) Alcohol or drug use Patients with Ejaculation disorder Systemic diseases (malignancy, thyroid disease, liver and gallbladder)
Cr>1.5 Sgot>80 Sgpt>80 Hb<10

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

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The way to select groups is that they will be assigned to groups based on block randomization. Blocks of size 4 are considered. So we will have six blocks containing AABB, ABAB, BBAA, BABA, ABBA, BAAB. Each block will also be randomly selected using a dice throw. For example, if thrown dice is 3, the BBAA block is considered, and therefore the first two patients are assigned to treatment B and the next two patients to treatment A. The dice will be thrown 20 times to complete the assignment of patients to the treatment groups. randomization is performed using the DOE option in MINITAB ver 15 software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Organizational Committee of Ethics in Biomedical Research

Street address

15 Khordad Blvd., Islamic Azad University, Qom

City

Qom

Province

Ghous

Postal code

۳۷۱۴۹۶۳۷۴۴

Approval date

2020-08-26, 1399/06/05

Ethics committee reference number

IR.IAU.QOM.REC.1399.021

Health conditions studied

1

Description of health condition studied

Oligoasthenotratospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm count

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

optical microscope

2

Description

sperm motility

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

optical microscope

3**Description**

sperm morphology

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

staining

4**Description**

sperm DNA fragmentation

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

optical microscope

5**Description**

protamine deficiency

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Fluorescent microscope

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

Follicle-stimulating hormone, Luteinizing Hormone, Testosterone

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

kit

2**Description**

Malondialdehyde

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

ELISA Kit

3**Description**

Total antioxidant capacity

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

ELISA Kit

4**Description**

Erectile quality

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

International Index of Erectile Function Questionnaire (IIEF)

5**Description**

Quality of sexual life

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Sexual Quality of Life Questionnaire (SQOL)

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

Intervention group: group of Zayesh Majoon (Twice a day, 8 grams each time), Royal Jelly capsule and Safof hefz capsule (made by Booali Daroo company) Twice a day for a 90-day period

Category

Treatment - Drugs

2**Description**

Control group: Sprigen oral supplement (contains vitamins C, E, D3, B1, B2, B6, B12, A, folic acid, Zinc, niacin, biotin, magnesium, L-carnitine, coenzyme Q10, inositol and N-acetylcysteine) and tamoxifen (2 tablets in the morning and evening) over a period of 90 days.

Category

Treatment - Drugs

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

Qom University Jihad Research Department of Jihad Daneshgahi Qom

Full name of responsible person

Leile Naserpour

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Qom, Shahid Karimi Blvd., Isar Town, Isar Square, Shabnam St.

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3716986466
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Leila Naserpour
Street address
Qom, Shahid Karimi Blvd., Isar Town, Isar Square, Shabnam St.
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Grant name

Grant code / Reference number

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

No

Title of funding source

BooaliDaroo pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Leila Naserpour
Position
Physiologist
Latest degree

Master

Other areas of specialty/work

Reproductive Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

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Position

Physiologist

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Person responsible for updating data

Contact

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Iranian academic center for education culture and research

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Fax**Email**

Leilanasery48@gmail.com

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