Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The study of the effect of combination herbal therapy (zayesh booalidaroo®+ 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 Safof hefz capsule in patients with oligoasthenotratospermia in the age range of 20 to 50 years.

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

Settings and conduct
To patients with oligo-stenotratozo 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 oligoasthenotratospermia(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 Receivingof routine drug male Infertility (90-day period) The second group Receivingof Zayesh Majoon, Royal Jelly capsule and Safof hefz capsule (made by BooaliDaroo 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 booalidaroo®+ 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

Ghoum

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

Oligoasthenotratosospermia

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 BooaliDaroo 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 Jahad Daneshghahi Qom
Full name of responsible person
Leile Naserpour
Street address
Qom, Shahid Karimi Blvd., Isar Town, Isar Square, Shabnam St.
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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
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Leilanasery48@gmail.com
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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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