Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of compund antioxidant medication (Sperigen tablet) on sperm DNA Fragmentation Index in infertile men aged 20 to 40 years of age

Protocol summary

Study aim
To determine and comparison of the amount of sperm DFI before and after treatment in the study group

Design
Clinical trial (before and after)study, without control group and not blinded ,single ,available sampling on 60 patients

Settings and conduct
The location of the studey is the infertility center and urology clinic of Ali-Ibn Abitaleb Hospital in Zahedan. Before starting treatment, sperm DFI test is performed and then patients are treated with Sperigen drug for 3 months.At the end of therapeutic intervention, the DFI test is taken from the patients again. The test is performed on the patient's semen.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Infertile men with impaired spermogram (Idiopathic spermogram) 2) age range 20 to 40 years 3)No hormonal disorder, anatomical or congenital anomalies in urogenital system 4) Lack of antioxidant medication usage and drugs affecting spermogran parmeters such as nitrofurantoin, corticosteroids, antineoplastic drug Exclusion criteria: 1)men with normal spermogram 2) drug use, cigarrette or waterpipe smoking 3)outside the specified age range 4)varicocele 5)patients with diabetes, thyroid problems and other internal disease affeting spermogram

Intervention groups
before starting the treatment ,sperm DFI test will be done and the patients will be treated with Sperigen drug for three months. At the end of the therapeutic intervention, the DFI test will be taken from the patient again.After analyzing the findings, the values obtained before and after taking the drug are compared and the effecriveness of the drug is determined on the amount of DFI.

Main outcome variables
Total sperm count; Total motile sperm count; Sperm morphology; DNA fragmentation Index

General information

Reason for update

Acronym
DFI(DNA Fragmentation Index)

IRCT registration information
IRCT registration number: **IRCT20230831059309N1**
Registration date: **2023-10-23, 1402/08/01**
Registration timing: **prospective**

Last update: **2023-10-23, 1402/08/01**
Update count: **0**

Registration date
2023-10-23, 1402/08/01

Registrant information

Name
narges ghaznavi jahromi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3632 1897

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-01, 1402/08/10

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of compund antioxidant medication (Sperigen tablet) on sperm DNA Fragmentation Index in infertile men aged 20 to 40 years of age

Public title
Effect of compund antioxidant medication (Sperigen tablet) on sperm DNA Fragmentation Index in infertile men aged 20 to 40 years
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile men with abnormal spermogram (Idiopathic) age range 20 to 40 years absence of hormonal, anatomical and congenital anomalies of the urogenital system, lack of antioxidant medication usage or drugs affecting spermogram parameters such as nitrofurantoin, corticosteroids and antineoplastic.
Exclusion criteria:
Men with normal spermogram use of drugs, cigarrette and waterpipe smoking patients outside the specified age range varicocele patients with Diabete, thyroid problem or any other internal disease affectting spermogram
Age
From **20 years** old to **40 years** old
Gender
Male

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Urology department office,Ali-Ibn Abitaleb Hospital,Khalij Fars Boulevard
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Approval date
2023-06-18, 1402/03/28
Ethics committee reference number
IR.ZAUMS.REC.1402.257

Health conditions studied

1

Description of health condition studied
male infertility
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
percentage of sperm DFI , total sperm count and total motile sperm in semen analysis.
Timepoint
Measurement of DNA fragmentation Index before starting and 3 months after taking the drug
Method of measurement
Sperm Chromatin Structure Assay lab test (SCSA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:patients treated with Sperigen drug (manufactured by Arvand Pharmed Company) one oral capsule every 12 hours for three months.This medicine contains of a variety of antioxidants such as vitamin C, vitamin B group, vitamin A, zinc, iron, folic acid, selenium, niacin, biotin and...
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center and Urology clinic of Ali-Ibn Abitaleb Zahedan Hospital
Full name of responsible person
Faramarz Fazali

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Khalij Fars Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
سودابه هاشم زهی
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Fax
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soodi1981@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
50
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
Zahedan University of Medical Sciences
Full name of responsible person
Narges Ghaznavi Jahromi
Position
Resident
Latest degree
Medical doctor
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Person responsible for updating data

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Other areas of specialty/work
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available