

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of compound 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 spermogram parameters such as nitrofurantoin, corticosteroids, antineoplastic drug Exclusion criteria: 1) men with normal spermogram 2) drug use, cigarette or waterpipe smoking 3) outside the specified age range 4) varicocele 5) patients with diabetes, thyroid problems and other internal disease affecting 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 effectiveness 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)

Phone

+98 71 3632 1897

Email address

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

Public title

Effect of compound 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, cigarette 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 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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Sponsors / Funding sources

1

Sponsor

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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
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

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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