Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating changes in sperm motility and expression levels of Dazl, Pmca4 and Bcl2 genes in asthenospermic individuals under the influence of zinc gluconate (ZG) supplementation

Protocol summary

Study aim

Investigating the expression levels of Dazl, Pmca4 and Bcl2 genes in asthenosperm individuals under the influence of zinc

Design

The clinical trial has a control group and an experimental group, two-way blinding was performed, the study was phase 2 and was performed on 60 patients. Random allocation was done using Excel software.

Settings and conduct

This research was conducted from 2019 to 2020 in Milad Fertility Clinic, Mashhad, (Iran) to evaluate and study the therapeutic effect of ZG administration on infertile men with asthenoteraspermia.The sample size was considered to be 30 people based on previous studies. According to the group they are in, they will receive ZG 30 mg per day for 3 months. people participating in the research and analyzing the data were blinded. Sperm samples were taken before and after the course and then evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men in the age range of 20 to 50 years who, according to expert opinion and based on WHO criteria, disorders related to asthenoteratospermia in sperm parameters were observed at an interval of 2 weeks Exclusion criteria: - People who had other special diseases and were diagnosed by a urologist and mentioned in their medical records. - Men who had taken special medicine or drugs in the last three months.

Intervention groups

The study was conducted on astheno-spermic individuals and the groups were divided and compared as follows: Intervention group 1 (control): patients with asthenospermia who received placebo. Intervention group 2 (experimental): patients with asthenospermia who received zinc gluconate supplementation.

Main outcome variables

Sperm motility

General information

Reason for update

Acronym

زینک گلوکونات یا zinc gluconate (ZG)

IRCT registration information

IRCT registration number: **IRCT20230205057334N1**
Registration date: **2023-09-10, 1402/06/19**
Registration timing: **retrospective**

Last update: **2023-09-10, 1402/06/19**
Update count: **0**

Registration date

2023-09-10, 1402/06/19

Registrant information

Name

Kiandokht Khoohestanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3893 2176

Email address

kian.dokht222@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-26, 1398/06/04

Expected recruitment end date

2020-08-27, 1399/06/06

Actual recruitment start date

2019-08-27, 1398/06/05

Actual recruitment end date

2021-01-21, 1399/11/02

Trial completion date

2021-02-20, 1399/12/02

Scientific title

Investigating changes in sperm motility and expression levels of Dazl, Pmca4 and Bcl2 genes in asthenospermic individuals under the influence of zinc gluconate (ZG) supplementation

Public title

Investigating the effect of zinc gluconate on sperm motility

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile men, despite having at least one year of unprotected intercourse, natural fertility did not occur in their wives. All men were married and in the age range of 20 to 50 years. According to the expert's opinion and based on the WHO criteria, disorders related to asthenotaratospermia should have been observed in the sperm parameters of at least two samples of their sperm analysis with an interval of 2 weeks.

Exclusion criteria:

single men People who had varicocele or other special disease and were diagnosed by a urologist and mentioned in their medical records. Men who had taken special medicine or drugs in the last three months. Infertile men who were not diagnosed by a neurogonadal specialist Participating in another study at the same time

Age

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

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

ejaculate sperm sample

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

ejaculate sperm sample

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This means that none of the patients know whether they have taken the drug or the placebo (the drug and the placebo were similar in terms of shape, color, and method of administration). The data analyst was also unaware of what the patients had consumed In the end, the spermogram information of each individual was only available to that person if necessary. The drug and placebo were similar in terms of shape, color, and method of administration, so blinding can be done at the participant level.

Placebo

Used

Assignment

Parallel

Other design features

In this study, asthenospermic individuals referred to the infertility center were divided into two intervention groups 1 (control), which included asthenospermic individuals who consumed placebo for 90 days, and intervention group 2 (experimental), which included asthenospermic individuals who consumed zinc gluconate supplements for 90 days.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad azad university

Street address

Mashhad, Sayad Shirazi Boulevard, Plate 42, Unit 4

City

mashhad

Province

Razavi Khorasan

Postal code

9177735868

Approval date

2019-04-05, 1398/01/16

Ethics committee reference number

IR.IAU.MSHD.REC.1398.199

Health conditions studied

1

Description of health condition studied

Asthenospermia

ICD-10 code

R86.9

ICD-10 code description

Unspecified abnormal finding in specimens from male genital organs

Primary outcomes

1

Description

sperm motility

Timepoint

In this study, the effect of zinc gluconate

supplementation on sperm motility after 90 days of starting to take this supplement was performed on asthenospermic subjects.

Method of measurement

spermogram reports of the patients .

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 people with asthenospermia who received zinc gluconate supplement (from Simorgh Daru Company) at a dose of 30 mg daily for 90 days.

Category

Treatment - Drugs

2

Description

Control group: 30 people with asthenospermia who received placebo daily for 90 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center, Mashhad, Iran

Full name of responsible person

Kiandokht Koohestanian

Street address

Sayad Shirazi St., Block 42, Unit 4

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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?

No

Title of funding source

Mashhad Azad University

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kiandokht Koohestanian

Position

Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Clinical reports of changes in spermogram and the effect of the drug used in intervention group 2 in this study can be shared after the individuals cannot be identified.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
For researchers and people working in the food and drug industry
Under which criteria data/document could be used
In order to make the dimensions of the research more complete, the documents of this study can be used
From where data/document is obtainable
Refer to the author's email address Kiandokht Kohstanian :(kian.dokht222@gmail.com)
What processes are involved for a request to access data/document
Sending an email to the authors of the article and explaining the commonality of the research with their proposed plan. The applicant will receive the answer after a week.
Comments
This study is retrospective