Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of alpha-lipoic acid antioxidant on sperm DNA Fragmentation in the treatment of recurrent abortion

Protocol summary

Study aim
The effect of alpha-lipoic acid on DNA fragmentation in the treatment of patients with recurrent abortion

Design
the controlled clinical trial, with parallel groups, two-way blind, randomized, on 40 patients. Computer random assignment list produced with PASS software.

Settings and conduct
This is a double-blind randomized clinical trial. Couples with a history of recurrent miscarriage who have been referred to Milad Infertility Center during 1300-1400 and meet the inclusion criteria are included in the study. The number of samples is about 20 people in each group. Individuals undergo initial semen liquid evaluation and their sperm are examined for DNA fragmentation index (DFI) by the SCSA method. In the case of DFI> 30%, using a simple randomization method and random number table, patients are assigned to two groups of placebo and intervention group. The study group received 300 mg of alpha-lipoic acid tablets 3 daily for 3 months. The placebo group also receives 300 mg tablets, very similar to the alpha-lipoic acid tablets 3 daily for 3 months.

Participants/Inclusion and exclusion criteria
Couples with a history of recurrent miscarriage with a DFI of more than 30% who refer to Milad Infertility Centers and meet the inclusion criteria are included in the study. Inclusion criteria: no history of PCO, no chronic ovulation, and no other tubular and anatomical causes, and no history of medical diseases and are willing to participate in the project. Subjects will be asked not to take any other supplements during the research. Exclusion criteria: Drug allergies and the occurrence of drug side effects such as hypotension and occasional hypoglycemia, anemia, and patients who did not take the drug regularly

Intervention groups
The study group received 300 mg of alpha-lipoic acid tablets, 3 daily for 3 months

Main outcome variables
DNA Fragmentation Index (DFI) sperm rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181030041503N4**
Registration date: **2021-08-18, 1400/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-18, 1400/05/27**
Update count: **0**

Registration date
2021-08-18, 1400/05/27

Registrant information

Name
Malihe Mahmoudinia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3882 9878

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of alpha-lipoic acid antioxidant on sperm DNA Fragmentation in the treatment of recurrent abortion

Public title
The effect of an antioxidant on couple fertility with recurrent abortion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Couples with a history of recurrent miscarriage and DFI >30% willingness to participate in the study Normal karyotype Thyroid, prolactin, and thrombophilic and phospholipid tests are normal

Exclusion criteria:
PCO and chronic anovulation presence of tubal and anatomical disease of the uterus Dissatisfaction with participation in the study presence of underlying disease Allergic drug reaction Side effects of the drug such as hypotension and occasional hypoglycemia and anemia Not taking the medicine regularly

Age
No age limit

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization -In this randomized clinical trial 40 patients, two groups were randomly assigned. -Method used to generate random allocation sequence by mentioning the name of the software or site used: Computer random assignment list produced with PASS software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is unaware of the treatment, patients are coded A and B based on random assignment, and the researcher gives the drug to the patient based on patient code A or B. The statistical consultant who analyzes the data is unaware of the grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad university of medical sciences Ethics committee

Street address
Vice chancellor of Research, Mashhad university of Medical Sciences, Mashhad University of Medical Sciences ,University Avenue.Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2021-07-06, 1400/04/15

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.209

Health conditions studied

1

Description of health condition studied
Male infertility

ICD-10 code
N46.9

ICD-10 code description
Male infertility, unspecified

Primary outcomes

1

Description
Examination of sperm DNA fragmentation

Timepoint
Before starting treatment and then, after 3 months of treatment

Method of measurement
Examination of blood samples using SCSA method

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group received 300 mg of alpha lipoic acid tablets made by the Raha Daroo Company, 3 daily for 3 months

Category
Treatment - Drugs

2

Description
The placebo group also receives 300 mg tablets, very similar to the alpha-lipoic acid tablets made by the School of Pharmacy, 3 daily for 3 months This medicine is provided by Raha Daroo Company
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Infertility center
Full name of responsible person
Nayereh Khadem
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Milad Infertility center, Mashhad, Khorasan Razavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen, Tafaghodi
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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 University of Medical Sciences
Proportion provided by this source
100
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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Shahabian moghaddam
Position
Specialized assistant for women
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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mahmoudinia

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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