

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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)

Phone

+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

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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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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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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

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

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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