Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effects of antioxidants on sperm molecular chromatin in recurrent pregnancy loss

Protocol summary

Summary

90 couples with unexplained recurrent miscarriage include in study. first spem analysis and chromatin tests to DNA fragmentation measure ,aniline blue, stained chromomycin A3 assessment will done. Then patient will divide in 3 groups. 1 control 2 recive vit E + selenium daily 3 recive vit E+ zinc daily. after 3 months second spem analysis and chromatin tests to DNA fragmentation measure ,aniline blue, stained chromomycin A3 assessment will done. result will analyse and compare between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704195261N3**
Registration date: **2017-05-08, 1396/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-08, 1396/02/18

Registrant information

Name
Tahereh Rahiminia
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

research and clinical center of infertility grant.

Expected recruitment start date

2017-05-04, 1396/02/14

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of antioxidants on sperm molecular chromatin in recurrent pregnancy loss

Public title

Evaluation the effects of antioxidants on sperm molecular chromatin in recurrent pregnancy loss

Purpose

Treatment

Inclusion/Exclusion criteria

All couples with recurrent pregnancy loss included. varicocele, Cryptorchidism, addicted male and heavy smokersT up of 50 years old male excluded from study.

Age

From **18 years** old to **49 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and clinical center of infertility. shahid sadoughi
Street address
Bu Ali street, Safaeyeh, Yazd
City
Yazd
Postal code
Approval date
2014-09-14, 1393/06/23
Ethics committee reference number
340

Health conditions studied

1

Description of health condition studied
Recurrent pregnancy loss
ICD-10 code
N96
ICD-10 code description
habitual or recurrent N96 without current pregnancy N96 Loss (of) pregnancy

Primary outcomes

1

Description
Sperm count
Timepoint
3 months
Method of measurement
2010WHO Guidelines

2

Description
Sperm motility
Timepoint
3 months
Method of measurement
2010 WHO Guidelines

3

Description
Sperm morpholigy
Timepoint
3 months
Method of measurement
2010 WHO Guidelines

4

Description
Dna fragmentation
Timepoint
3 months
Method of measurement
2010 WHO Guidelines

5

Description
Protamine ratio
Timepoint
3 months
Method of measurement
2010 Who Guidelines

6

Description
Histone ratio
Timepoint
3 montha
Method of measurement
2010 WHO Guidelines

Secondary outcomes

empty

Intervention groups

1

Description
control
Category
Lifestyle

2

Description
vit E(400 mg)+ selenium(200 mg), daily. 3 months
Category
Treatment - Drugs

3

Description
vit E(400 mg)+ zinc(30 mg), daily, 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences.
Full name of responsible person
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Ali Reza Talebi
Street address
Bu Ali street, Safaeyeh, Yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Soheila Pourmasumi
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00
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty