

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 sperm 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 receive vit E + selenium daily 3 receive vit E+ zinc daily. after 3 months second sperm 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

Country

Iran (Islamic Republic of)

Phone

+98 21 4490 4272

Email address

t_rahiminia@razi.tums.ac.ir

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

Position

Ph.D candidate

Other areas of specialty/work

Street address

Bu Ali street, Safaeyeh, Yazd

City

Yazd

Postal code

Phone

+98 35 3824 7087

Fax

Email

spourmasumi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pourmasumi

Full name of responsible person

Soheila

Position

Ph.D candidate

Other areas of specialty/work

Street address

Bu Ali street, Safaeyeh, Yazd

City

Yazd

Postal code

Phone

+98 35 3824 7087

Fax

Email

spourmasumi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Pourmasumi

Full name of responsible person

Soheila

Position

Research and Clinical Center for Infertility, Shahid
Sadoughi University of Medical Sciences

Other areas of specialty/work

Street address

Ph.D candidate

City

Postal code

Phone

00

Fax

Email

Web page address

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