

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effects of antioxidative treatments on sperm DNA fragmentation and pregnancy results in IUI

Protocol summary

Summary

The objective of this random controlled clinical trial, sampling in single reference center and convenient sampling, is to investigate the effects of antioxidative treatments on pregnancy results. In this study 150 infertile candidates for IUI which qualified for the inclusion criteria: normal hormonal analysis; at least one open fallopian tube in hysterosalpingography; the absence of cervicitis and exclusion criteria: Irregular menstruation; galactorrhea; abnormal hysterosalpingography, will randomly assigned into intervention or control group. The patients in the intervention group will receive vitamin C, E, Zinc and w3 supplement and control group will received no treatment. DNA fragmentation and its effects in the results of pregnancy with IUI, will evaluate in 5 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306115942N2**

Registration date: **2013-08-26, 1392/06/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name

Aliye Ghasemzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9160

Email address

gasemzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-06-10, 1392/03/20

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of antioxidative treatments on sperm DNA fragmentation and pregnancy results in IUI

Public title

Effects of antioxidative treatments on pregnancy results

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: normal hormonal analysis; infertile women candidates for IUI method; age at least 25 years old and less than 40years old; body mass index minimum 19 kg/m² and less than 30 kg/m²; at least one open fallopian tube in hysterosalpingography; the absence of cervicitis or clinical cervical lesion; SDF (Sperm DNA Fragmentation) less than 30%; the absence of infection in accessory glands; lack of drug addiction and smoking; the absence of varicocele. Exclusion criteria: Irregular menstruation; Galactorrhea; abnormal hysterosalpingography; obstruction in fallopian; adhesion of fallopian; past medical peritoneal surgery; infection in accessory glands

Age

From **25 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Building No.2 of Research Vice-Chancellor,Tabriz
University of Medical Sciences,Tabriz

City

Tabriz

Postal code

Approval date

2012-09-11, 1391/06/21

Ethics committee reference number

5498/4/5

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male

2

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

3

Description of health condition studied

Infertility

ICD-10 code

N97.3

ICD-10 code description

Female infertility of cervical origin

Primary outcomes

1

Description

sperm DNA fragmentation

Timepoint

Before interposition, 2 month after interposition

Method of measurement

Observation with optic microscope

Secondary outcomes

1

Description

Pregnancy outcomes

Timepoint

Two weeks after IUI

Method of measurement

Pregnancy occurrence after positive blood HCG assay

Intervention groups

1

Description

one group,vitamin C orally administered daily with 1000 mg dosage for two month.

Category

Treatment - Drugs

2

Description

Control group without any treatment

Category

Treatment - Drugs

3

Description

one group,zn Supplement orally administered daily with 30mg dosage for two month.

Category

Treatment - Drugs

4

Description

one group,vitamin E orally administered daily with 400

mg dosage for two month.

Category

Treatment - Drugs

5

Description

one group,W3 Supplement orally adminstrated daily with1000mg dosage for two month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Al-Zahra Hospital

Full name of responsible person

Doctor Aliye Ghasemzadeh

Street address

Al Zahra Hospital, Bagshomal Crossroad, Southern
Artesh St., Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Al-Zahra Hospital, Bagshomal Crossroad, Southern
Artesh St., Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Aliye Ghasemzadeh

Position

Gynecology and Obstetrics Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Aliye Ghasemzadeh

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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