

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluating the relative expression and effects of methyltransferase on global genomic methylation rate in sperms of Oligoasthenoteratozoospermia patients with protamine deficiency before and after of folic acid uptake

Protocol summary

Summary

The goal is to evaluate semen parameters and sperm chromatin DNA methylation after taking folic in men with severe sperm abnormalities. Among men referred to Yazd Research Institute for Infertility, 50 men who are seeking treatment for infertility, sperm analysis has fewer parameters according to World health Organisation criteria and protamine deficiency (CMA3) test are selected and divided into two groups and after medication will be reviewed. The 30 men who have normal parameters and are normal CMA3 will be in a control group. In the intervention group after andrology assessments will be randomly divided into two groups of 25 patients, treated with vitamin E and selenium with or without folic acid for two months . After washing the samples in different groups, the viability of sperm with eosin,cellular tests to evaluate sperm chromatin integrity will be done. These tests include aniline blue, toluidine blue. To evaluate genetically, sperm samples will be prepared by with buffer and divided into two parts and stored frozen at -80 ° C. After preparation of the samples, RNA extraction protocol is performed. Then specimens are examined by PCR Real time. After two months, the patients will be genetically re-examination and then the results will be discussed between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507285261N2**

Registration date: **2016-03-27, 1395/01/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-27, 1395/01/08

Registrant information

Name

Tahereh Rahiminia

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Yazd Institute of Reproductive Sciences

Expected recruitment start date

2015-08-22, 1394/05/31

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the relative expression and effects of methyltransferase on global genomic methylation rate in sperms of Oligoasthenoteratozoospermia patients with protamine deficiency before and after of folic acid uptake

Public title

ffects of the relative expression of genes of sperm DNA methyltransferase on global methylation in patients with severe sperm abnormalities before and after folic acid uptake

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria includes severe sperm parameters and protamine disrupted, age less than 40, avoiding the use of drugs or alcohol, and varicocele Exclusion criteria: Unwillingness to continue during study,Diabetes,Blood Hypertension, obesity

Age

From **20 years** old to **40 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)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Yazd Institute for Reproductive Sciences

Street address

Bu Ali St, Safaieh

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8916877391

Approval date

2014-05-13, 1393/02/23

Ethics committee reference number

IR.SSU.RSI.RES.1394.8

Health conditions studied**1****Description of health condition studied**

Oligospermia

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Sperm parameters including count, motility, morphology

Timepoint

Two months after the intervention

Method of measurement

Microscopic examination of sperm

2**Description**

Relative gene expression of methyltransferase

Timepoint

Two months after the intervention

Method of measurement

PCR Real time

3**Description**

Phosphate group condensation

Timepoint

Two months after the intervention

Method of measurement

Toluidine Blue

4**Description**

Protamin deficiency

Timepoint

Two months after the intervention

Method of measurement

CMA3

Secondary outcomes**1****Description**

Flatulence, insomnia

Timepoint

Two month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

folic acid tablet in intervention group

Category

Treatment - Drugs

2

Description

no intervention in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Infertility Center

Full name of responsible person

Tahereh Rahiminia

Street address

Yazd Infertility Center

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd research and clinical center for infertility

Full name of responsible person

Dr Khalili

Street address

Bu Ali, Safaieh

City

Yazd

Grant name

Grant code / Reference number

-

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

Yes

Title of funding source

Yazd research and clinical center for infertility

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

Yazd Infertility Center

Full name of responsible person

Tahereh Rahiminia

Position

PhD student

Other areas of specialty/work

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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*