Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Myo-inositol on Sperm Parameters and Fertility Rate in Patients with Oligoasthenospermia Treated with IUI: A Randomized Clinical Trial

Protocol summary

Study aim

-Evaluation of the effect of myoinositol on sperm movement in oligoastenospermia؛ -Evaluation the effect of myoinositol on sperm DNA fragmentation in oligoastenospermia؛ -evaluation of the effect of myoinositol on sperm morphology in oligoastenospermia؛ -Evaluation of the effect of myoinositol on fertility in oligoastenospermia.

Design

Two groups of patients with inositol and non-inositol triple blind randomized Clinical trial

Settings and conduct

for IUI Treatment Semen sample removed after 48-72h from the ejaculation method and then placed in a 37-degree incubator for 30 minutes. After liquefying the sample, the sperm analysis with gradient method (sill select plus)After the sperm separation step, the subjects were randomly divided into two groups of 30, after examining the spermatic parameters, the parameters were examined and recorded. Patient, physician and responsible for evaluation of sperm parameters, did not know the type of sample at the IVF center in Shahid Akbar Abadi Hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: -Couples who have not been pregnant for one year؛ -hysterosalpingography and hormonal testing of all women were uncomplicated؛ -men have oligo or asthenospermia. Exclusion criteria: 1- Sever male factor (male Oligo Stato) 2. Untreated hormonal problem 3. BMI higher than 35 4. Age of a woman older than 38 years

Intervention groups

In the first group: no intervention was performed and the sperms were incubated for 2 hours at 37 ° C In the .5 ml medium, the medium of flushing is encapsulated in the kit. To the second group: two milliliters of myoinositol are added and incubated for 37 ° C in the incubator for 2 hours.

Main outcome variables

-Number of live sperm (viability)؛ -Sperm motility؛ -Morphology؛ -Agglutination؛ -Volume؛ -Acidity؛ -Duration of liquefaction؛ -Dfi؛ -Fertility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181031041519N1**
Registration date: **2019-01-06, 1397/10/16**
Registration timing: **retrospective**

Last update: **2019-01-06, 1397/10/16**
Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Seyyedeh Tahere Ghazimirsaeed

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-03-20, 1395/12/30

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Effect of Myo-inositol on Sperm Parameters and Fertility Rate in Patients with Oligoasthenospermia Treated with IUI: A Randomized Clinical Trial

Public title

The effect of Myo-inositol on the treatment of male infertility in couples under IUI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Couples who have not been pregnant for one year In the studies included hysterosalpingography and hormonal testing all women were uncomplicated Men have oligo or asthenospermia.

Exclusion criteria:

Sever male factor (Oligo Stoenou men) Untreated hormonal problem BMI higher than 35 The age of a woman is over 38 years old

Age

To **38 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

- Patients were randomly divided into two groups using Excel software - We used stratified randomization - Each code contained in sealed envelopes was provided to clinical care

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are divided into two groups of case and control according to the random numbers table, and patient, the physician and responsible for examining the sperm parameters didnt know which sample containing or not containing inositol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences.Hemmat Ave.Tehran Town

City

tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.IUMS.FMD.REC1396.9211290014

Health conditions studied

1

Description of health condition studied

Male infertility due to oligoastenospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm motility Morphology Agglutination Volume Acidity Duration of liquefaction Dfi

Timepoint

sperm sample day After sample incubation Two hours after treatment with myo-inositol

Method of measurement

Examination of sperm samples under a microscope

Secondary outcomes

1

Description

Fertility

Timepoint

Two weeks after iui

Method of measurement

Serum Beta HCG

Intervention groups

1

Description
Semen sample removed after 48-72h from the ejaculation method and then placed in a 37-degree incubator for 30 minutes. After liquefying the sample, the sperm analysis with gradient method (sill select plus)After the sperm separation step, the subjects were randomly divided into two groups. Intervention Group: in the semen of this group, add .5 milliliter of myoinositol at a concentration of 2 mg/ml and incubate for 37 °C in the incubator for 2 hours.

Category
Treatment - Drugs

2

Description
Control group: Semen sample removed after 48-72h from the ejaculation method and then placed in a 37-degree incubator for 30 minutes. After liquefying the sample, the sperm analysis with gradient method (sill select plus)After the sperm separation step, the subjects were randomly divided into two groups. Control Group: in the semen of this group not add myoinositol, but only incubate for 37 °C in the incubator for 2 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Akbar Abadi Hospital, IVF Center

Full name of responsible person
Seyyedeh Tahereh ghazimirsaeed

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Seyyedeh Tahereh Ghazi mirsaeed

Position
resident

Latest degree
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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable