

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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 myo-inositol on sperm movement in oligoasthenospermia!
-Evaluation the effect of myo-inositol on sperm DNA fragmentation in oligoasthenospermia!
-evaluation of the effect of myo-inositol on sperm morphology in oligoasthenospermia!
-Evaluation of the effect of myo-inositol on fertility in oligoasthenospermia.

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 spermatoc 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 myo-inositol 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 8831

Email address

ghazimirsaeed.st@tak.iuums.ac.ir

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

۱۴۳۹۶۱۴۵۳۵

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 oligoasthenospermia

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

Street address

shahid akbar abadi Hospital.molavi St.Tehran

City

tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5560 6034

Email

akbarabadihosp@yahoo.com

Web page address

http://crtai.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakoti

Street address

Iran, Tehran, Hemat Highway, Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2553

Fax

+98 21 8670 2553

Email

PR@iums.ac.ir

Web page address

http://vcr.iums.ac.ir

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

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

no8.colop 18 Ally.imam montazer St.Satarkhan St

City

tehran

Province

Tehran

Postal code

1444933611

Phone

+98 21 8826 5089

Email

dr.ghazi83@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

dr.zahra doroodian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Rasul akram Hospital Satarkhan St

City

tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6655 9595

Email

dr.ghazi83@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyedeh tahereh ghazimirsaeed

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

no8.colop18Ally.imam montazer St

City

tehran

Province

Tehran

Postal code

4933611144

Phone

+98 21 8826 5089

Email

dr.ghazi83@gmail.com

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