Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Effects of Myo-inositol on IVF outcomes in poor responders undergoing intracytoplasmic sperm injection and comprission with folic acid:a randomised clinical trial

Protocol summary

Study aim

effect of myoinositol on oocyte number; effect of myoinositol on pregnancy rate; effect of myoinositol on abortion rate

Design

This randomized clinical trial is performed on148 infertile patients with low ovarian response . Myoinositol 4 gr with Folic acid 400 microgram are administered in study gorup and placebo with Folic acid 400 microgram are administered one month before the cycle in two groups. . Ovarian stimulation with antagonist protocol will be started on day 2 or 3 of menstrual cycle in both groups. Embryo transfer will be done in day 2-3 after ICSI.

Settings and conduct

This clinical tria isl performed in Infertility and IVF ward, Taleghani hospital. 148 infertile patients with low ovarian response are recruited into the study in two groups according to randomization method. Myoinositol 4 gr with Folic acid 400 microgram administer in study gorup and placebo with Folic acid 400 microgram are administered one month before the cycle in two groups. Consent form were taken from participants were taken after awareness of them.Neither reserchер and no participants didnot aware type of drug.

Participants/Inclusion and exclusion criteria

Age below 45 years; Body mass index (BMI) between 20-30; low ovarian reserve [both ovarian AFC below 7 or AMH below 1.1 ng/ml or low ovarian response in previous cycle (below 3 oocyte)]; none history of allergy to Myo-inositol Exclusion criteria: unwillingness to continue

Intervention groups

Administration inofolic in poor responder patients before IVF cycle:Administration of inofolic will start one month before IVF cycle and it will continue on stimulation phase. Placebo and folic acid will administer in control group

Main outcome variables

Number of oocyte,clinical pregnancy,Abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160722029027N8**
Registration date: **2019-07-27, 1398/05/05**
Registration timing: **retrospective**

Last update: **2019-07-27, 1398/05/05**
Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Leila Nazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2271 8000

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Myo-inositol on IVF outcomes in poor responders undergoing intracytoplasmic sperm injection and comprission with folic acid:a randomised clinical trial

Public title

Effects of Myo-inositol in poor responder patients undergoing intracytoplasmic sperm injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Age below 45 years Body mass index (BMI) between 20-30 low ovarian reserve [both ovarian AFC below 7 or AMH below 1.1 ng/ml or low ovarian response in previous cycle (below 3 oocyte) none history of allergy to Myo-inositol

Exclusion criteria:

unwillingness to continue

Age

To **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were assigned into two groups, using permuted block randomization method with size of block of two. Package block rand in R statistical software was used for preparing randomization list.

Blinding (investigator's opinion)

Double blinded

Blinding description

this is a double-blinded study in which both patients and the conductor specialist were blinded about the contents of dug boxes. Each of drug boxes contains either Myo-inositol powder and placebo tablet (group A) or folic-acid tablet and placebo powder (group B). Neither specialist nor patients were informed about the boxes contents, just the drug company was informed about the study groups. Specialist assigned patients to one of these boxes according to the randomization list. In order to blind patients, no names was typed on the tablet or powder container.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman St, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2016-04-19, 1395/01/31

Ethics committee reference number

IR.SBMU. MSP.REC.1395.20

Health conditions studied

1

Description of health condition studied

Noninflammatory disorders of female genital tract

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description

Number of metaphase II oocyte

Timepoint

Time of oocyte pick up

Method of measurement

According to embryolog criteria

2

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

Serum βHcG test

Secondary outcomes

1

Description
Clinical pregnancy
Timepoint
4 weeks after embryo transfer
Method of measurement
Transvaginal ultrasound

2

Description
Ongoing pregnancy
Timepoint
10 weeks after embryo transfer
Method of measurement
Vision fetal heart beat in ultrasound

Intervention groups

1

Description
Intervention group: Myoinositol 4 gr and Folic Acid 400 microgram was administered one month before the cycle and ovarian stimulation with antagonist protocol will be started on day 2 or 3 of menstrual cycle
Category
Treatment - Drugs

2

Description
Control group: Placebo and Folic Acid 400 microgram was administered one month before the cycle and ovarian stimulation with antagonist protocol will be started on day 2 or 3 of menstrual cycle
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility and IVF ward of Talghani hospital
Full name of responsible person
Leila Nazari
Street address
Yaman St, Velenjak, Chamran highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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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
Vice Chancellor for research of Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Nazari
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
تعداد اووسیت -دوز گنادوترو پین مصرفی
When the data will become available and for how long
without restriction
To whom data/document is available
All researchers
Under which criteria data/document could be used
With permission from the author responsible
From where data/document is obtainable
With permission from the author responsible
What processes are involved for a request to access data/document
Email to author responsible
Comments
Effective drug in IVF