

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

Number of oocyte,clinical pregnancy,Abortion

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 on 148 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 resercher and no participants didnt 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

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)

Phone

+98 21 2271 8000

Email address

nazari@sbmu.ac.ir

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 compression 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 drug 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 β HcG test

Secondary outcomes

nazari@sbmu.ac.ir

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

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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

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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 اوسیت -دور گنادوترو بین 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