

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Dec 2023

The Effect of Myo-inositol on fertility rates in Poor ovarian Responder Women undergoing Assisted Reproductive technique

Protocol summary

Study aim

The Effect of Myo-inositol on fertility rates in Poor ovarian Responder Women undergoing Assisted Reproductive technique

Design

A randomized controlled clinical trial with double blinded parallel groups. Randomization was centralized and computerized with concealed randomization sequence.

Settings and conduct

This study is performed on women with poor ovarian responder referred to infertility center of Bandar Abbas University of Medical Sciences. All patients will receive infertility treatment with antagonist protocol after receiving the drug. After ovulation induction, the number of oocytes, fertilization rate and pregnancy rate are checked. Blinding: People in the control group receive folic acid powder similar to the form of Inofolic produced by a reputable private pharmaceutical company. Both groups of patients, clinical researcher and data analyzer, do not know the type of treatment.

Participants/Inclusion and exclusion criteria

Infertile women of childbearing age referring to the Infertility Center who have one of the criteria of poor ovarian responder as below: Antral follicle count less than 7 Anti-Mullerian hormone level Less than 1.2 ng / ml
Age over 40 years

Intervention groups

Intervention is myo-inositol. Intervention group: Poor ovarian responder patients who receive Inofolic powder (myo-inositol + folic acid) 4g/daily-12 weeks. Control group: Poor ovarian responder patients who receive folic acid 400mg/ daily-12 weeks.

Main outcome variables

Oocyte quality, oocytes number, Fertilization rate, Embryo quality, Clinical and Biochemical pregnancy rate, Abortion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039668N1**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **retrospective**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

Fatemeh Eini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 7192

Email address

f.eini13@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2020-01-20, 1398/10/30

Trial completion date

2020-01-20, 1398/10/30

Scientific title

The Effect of Myo-inositol on fertility rates in Poor ovarian Responder Women undergoing Assisted Reproductive technique

Public title

The Effect of Myo-inositol on fertility rates in Poor ovarian Responder Women undergoing Assisted Reproductive technique

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All women of reproductive age with reduced ovarian reserve (number of Antral follicles less than 7) All women of reproductive age with decreased in anti-mullerian hormone to less than 1.2 ng/ml All women of reproductive age over than 40 years Having one of the above criteria is a prerequisite for entry into the study

Exclusion criteria:

Presence of endocrine and metabolic disorders such as polycystic ovary syndrome, hyperprolactinemia, diabetes and thyroid dysfunction Pelvic pathology such as hydrosalpinx, uterine anomaly Stages III to IV endometriosis and fibroma Male factors infertility such as Oligo-Astheno-Teratozoospermia (OAT) or Azoospermia

Age

From **20 years** old to **43 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

case of this study randomly assigned to two same groups in block balanced randomization using Random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding: patients in the control group receive folic acid powder with the same appearance as that produced by a private pharmaceutical company. Patients in both treatment groups (myo-inositol) and control (folic acid) had the same treatment conditions and were randomly divided into two groups. The inclusion and exclusion criteria were the same for both groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Fertility and Infertility Research Center

Street address

Fertility and Infertility Research Center, Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2019-03-21, 1398/01/01

Ethics committee reference number

IR.HUMS.REC.1398.393

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

Poor Ovarian Responder

ICD-10 code

E28.39

ICD-10 code description

Other primary ovarian failure

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

Oocyte Quility

Timepoint

2-3 hr after oocyte collection

Method of measurement

Microscopic Evaluation

2**Description**

Fertilization Rate

Timepoint

24 hr after Injection

Method of measurement

Microscopic Evaluation

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

Biochemical Pregnancy Rate

Timepoint

2 weeks after embryo transfer

Method of measurement

B-HCG evaluation

2**Description**

Clinical pregnancy rate

Timepoint

7 weeks after embryo transfer

Method of measurement

Sonography for fetal heart rate

Intervention groups**1****Description**

Intervention group: Daily oral administration of 4gr of Inofolic powder (myoinositol + folic acid) for 12 weeks in patients with poor ovarian responder

Category

Treatment - Drugs

2**Description**

Control group: Daily oral administration of 400 micrograms of folic acid powder for 12 weeks in patients with poor ovarian response

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Treatment Center of the Payambar Azam

Full name of responsible person

Dr Maryam Azizi

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Jomhour Street

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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

Bandare-abbas University of Medical Sciences

Proportion provided by this source

50

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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Azizi Kutenaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient's lack of consent

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available