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

his 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 bellow: 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 Infolic powder (myoinositol + 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]nofolic 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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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
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Person responsible for updating data

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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