

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Feb 2026

### 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-Asthenozoospermia (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 Jnofolic 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

**Street address**

Jomhour Street

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**Province**

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**Postal code**

7919915519

**Phone**

+98 76 3333 0755

**Email**

Maryamazikut86@gmail.com

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

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Maryam Azizi kutenaei

**Street address**

Jomhour Street

**City**

Bandar Abbas

**Province**

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**Email**

maryamazikut86@gmail.com

**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

**Street address**

Jomhour

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Maryam Azizi Kutenaeei

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Province**

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7919915519

**Phone**

+98 76 3333 0755

**Email**

Maryamazizikut86@gmail.com

## 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