

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the effect of pyridostigmine on controlled ovarian stimulation cycles in individuals with poor ovarian response

#### Protocol summary

##### Study aim

Determining the effect of Pyridostigmine on controlled ovarian stimulation cycles in individuals with poor ovarian response

##### Design

This is a phase III, randomized, single-blind, parallel-group, placebo-controlled clinical trial conducted on 110 patients.

##### Settings and conduct

This RCT will be conducted at the infertility and IVF clinic in Imam Khomeini Hospital, TUMS. As the patients in the intervention group are blinded to the other group type and will be separately subjected to the intervention, the intervention will be single-blind.

##### Participants/Inclusion and exclusion criteria

Women with a history of poor response to ovarian stimulation in previous cycles who are willing to undergo a new cycle are eligible to participate in this study. However, individuals with a body mass index greater than 30, respiratory diseases (such as asthma, chronic obstructive pulmonary disease), renal disease, slow or irregular heartbeat, a history of slow bowel movements and constipation (due to the possibility of delayed drug metabolism), or metabolic disorders, taking any other cholinergic drug and/or psychotropic medications and corticosteroids, suffering from stage III-IV endometriosis, or having a history of any allergic reactions, will not be included in this study.

##### Intervention groups

After obtaining informed consent, the patients will be randomly assigned to two groups, A and B. Group A or the intervention group will receive controlled ovarian stimulation treatment with Pyridostigmine at a dose of 120 mg (two 60 mg tablets) orally per day starting from day 1 of the stimulation cycle and will continue until the trigger HCG injection. Group B or the control group will receive routine treatment, which consists of daily administration of a maximum of 150 units of gonadotropin.

#### Main outcome variables

Retrieved Oocytes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100518003950N8**

Registration date: **2023-08-05, 1402/05/14**

Registration timing: **prospective**

Last update: **2023-08-05, 1402/05/14**

Update count: **0**

##### Registration date

2023-08-05, 1402/05/14

##### Registrant information

##### Name

Mina Jafarabadei

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1616

##### Email address

jafarabadi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-06, 1402/05/15

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of pyridostigmine on controlled ovarian stimulation cycles in individuals with poor ovarian response

**Public title**  
Investigating the effect of pyridostigmine in individuals with poor ovarian response

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women with a history of poor response to ovarian stimulation in previous cycles who are willing to undergo a new cycle.  
**Exclusion criteria:**  
BMI more than 30 Respiratory diseases (such as asthma, COPD), renal disease, slow or irregular heartbeat, a history of slow bowel movements and constipation (due to the possibility of delayed drug metabolism), or metabolic disorders. Taking any other cholinergic drug. Endometriosis, stage III-IV History of allergic reactions Taking psychotropic medications and corticosteroids

**Age**  
No age limit

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **110**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible patients will be randomly allocated into two groups using 4-block randomization with a 1:1 allocation ratio. The allocation will be as follows: AABB-ABBA-ABAB-BBAA-BAAB-BABA-... This allocation will continue until the desired sample size (55 participants per group) is achieved.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The patients in the intervention group are blinded to the other group type and will be separately subjected to the intervention.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

##### Street address

Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

#### Approval date

2023-07-19, 1402/04/28

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1402.173

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Retrieved Oocytes

#### Timepoint

36 hours after receiving the ovulation induction

#### Method of measurement

Laboratory count

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will receive controlled ovarian stimulation treatment with Pyridostigmine at a dose of 120 mg (two 60 mg tablets) orally per day starting from day 1 of the stimulation cycle and will continue until the trigger HCG injection.

#### Category

Treatment - Drugs

## 2

### Description

Control group: The control group will receive routine treatment, which consists of daily administration of a maximum of 150 units of gonadotropin.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The infertility and IVF clinic in Imam Khomeini Hospital, TUMS.

##### Full name of responsible person

Mina Naghi Jafarabadi

##### Street address

Keshavarz Blvd, Imam Khomeini hospital

##### City

Tehran

##### Province

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##### Postal code

1419733141

##### Phone

+98 21 6119 0000

##### Email

minajaf@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Fotoohi

##### Street address

6th floor., Central Organization of TUMS., Qods Ave., Keshavarz Blvd.

##### City

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##### Postal code

1276141690

##### Phone

+98 21 8163 3685

##### Email

vcr@tums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mina Jafarabadi

##### Position

Associate professor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Infertility Research Center, Imam Khomeini Hospital, Keshavarz Boulevard

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mina Jafarabadi

##### Position

Assistant professor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

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Keshavarz Blvd, Immam Khomeini Hospital , vali-Asr Hospital.

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mina Jafarabadi  
**Position**  
Assistant Professor  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Keshavarz BIVd, Imam Hospital, Vali-Asr Hospital.  
**City**  
Tehran  
**Province**  
Tehran

## 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**  
No more Information.  
**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