Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Akbar Fotoohi
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6th floor., Central Organization of TUMS., Qods Ave., Keshavaraz Blvd.
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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
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
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Latest degree

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Other areas of specialty/work

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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

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