

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of sitagliptin and metformin on oocyte and embryo quality, number of retrieved and fertilized oocyte and embryo the Polycystic ovary syndrome (PCOS) insulin-resistant women undergoing In vitro fertilization (IVF)

Protocol summary

Study aim

Comparison of the effect of Sitagliptin and Metformin on oocyte and embryo quality, number of retrieved and fertilized oocyte and embryo the PCO insulin-resistant women undergoing IVF

Design

Clinical trial, with parallel groups, double-blind, phase three, randomized, where 76 patients will be randomly assigned to two groups of 38 people with the size of blocks of 8.

Settings and conduct

The studied population are women aged 18-40 referring to the Fatima Zahra Infertility Research Center of Babol. Patients are randomly divided into two intervention groups by block method. Intervention group 1: PCO women treated with sitagliptin (Elixir Pharmaceutical Company) 100 mg three times a day Intervention group 2: PCO women treated with Metformin (Zagros Daru Company) 500 mg 3 times a day

Participants/Inclusion and exclusion criteria

Diagnosis of PCOS based on Rotterdam criteria: Age 18 to 40 years: BMI $\geq$ 20: Insulin resistant: IVF candidate: Not taking drugs that are effective on the activity of two drugs at this time in the last 3 months: Not taking weight-loss drugs or having any slimming diet or regular aerobic exercise in the last 3 months: Not receiving assisted reproductive treatments in the last 3 months
Exclusion Criteria: Getting pregnant during the study: The patient's lack of consent to enter or the patient's lack of cooperation in taking the medicine: smoking

Intervention groups

Intervention group 1: PCO women treated with sitagliptin (Elixir Pharmaceutical Company) 100 mg three times a day Intervention group 2: PCO women treated with Metformin (Zagros Daru Company) 500 mg 3 times a day

Main outcome variables

oocyte and embryo quality (average number of recovered, fertilized oocyte and embryos formed with excellent quality)

General information

Reason for update

Due to the corona pandemic and lack of referrals of sufficient number of patients. It was not possible to realize the expected sample size. Therefore, according to the opinion of the statistical consultant, the sample size has been changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055607N1**
Registration date: **2022-08-04, 1401/05/13**
Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**

Update count: **1**

Registration date

2022-08-04, 1401/05/13

Registrant information

Name

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Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-13, 1401/05/22

Expected recruitment end date

2023-08-13, 1402/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of sitagliptin and metformin on oocyte and embryo quality, number of retrieved and fertilized oocyte and embryo the Polycystic ovary syndrome (PCOS) insulin-resistant women undergoing In vitro fertilization (IVF)

Public title

The effect of sitagliptin and metformin on the quality of oocyte and embryos, the number of retrieved oocyte

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Polycystic ovary syndrome (PCOS) based on Rotterdam criteria Age 18 to 40 years BMI $\geq$ 20 Insulin resistant In vitro fertilization (IVF) candidate Not taking drugs that are effective on the activity of two drugs at this time in the last 3 months Not taking weight-loss drugs or having any slimming diet or regular aerobic exercise in the last 3 months Not receiving assisted reproductive treatments in the last 3 months

Exclusion criteria:

Getting pregnant during the study The patient's lack of consent to enter or the patient's lack of cooperation in taking the medicine smoking

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to two groups of 38 using a block of 8 and a ratio of 1:1. In order to generate the allocation sequence, the free website com.randomization.www will be used. The obtained sequence will be written on separate sheets and will be placed in closed envelopes and will be provided to the main researcher to conduct the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicines are in capsule form. For the purpose of blinding, the capsules containing sitagliptin are chosen to be completely identical to metformin capsules so that they are completely similar in terms of smell, color and shape. The capsules containing these drugs are placed in cans of the same shape and size, and then a 3-digit code is written on each can. After the patient enters the study, one of these cans is assigned to the patient and the code on the can is on the patient file (study checklist) is written. Opening the codes will be done after completing the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

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471764136

Approval date

2022-07-11, 1401/04/20

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.115

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

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

Oocyte and embryo quality

Timepoint

Two months after the start of the intervention

Method of measurement

The average number of retrieved oocyte, fertilized and formed embryos with excellent quality

Secondary outcomes

empty

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

Intervention group: Intervention group 1: PCO women treated with sitagliptin (Elixir Pharmaceutical Company) 100 mg three times a day

Category

Treatment - Drugs

2**Description**

Intervention group: PCO women treated with Metformin (Zagros Daru Company) 500 mg 3 times a day

Category

Treatment - Drugs

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

Fatemehzahra Fertility & reproductive Health Reseach Center

Full name of responsible person

Marmar Firouzpour

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol 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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Sedigheh Esmaeilzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available