Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative Study on Therapeutic Effect of Sitagliptin-Metformin and Metformin in Infertile Women with polycystic ovary syndrome (PCOS) undergoing intra-cytoplasmic sperm injection (ICSI)

Protocol summary

Study aim
we will evaluate and compare the efficacy of Sitagliptin-Metformin, on PCOS patients undergoing intracytoplasmic sperm injection(ICSI).

Design
a randomized clinical trial, placebo con- trolled pilot study

Settings and conduct
This study was conducted in Infertility clinic of Mahdiyeh Educational Hospital, Tehran. Patients in the four groups receive the drug 2 months before the start of the ovulation cycle, and treatment will continue until the day of the oocyte aspiration. The drug provide by midwife to patients and both patient and physician blind to the treatment regimen. The population randomly divide into four groups.The ovulation induction stimulate with GnRh antagonist

Participants/Inclusion and exclusion criteria
In this study, Infertility due to polycystic ovary syndrome at the age of 25 to 35 is considered as the inclusion criteria.. Hypersensitivity to either metformin or Sitagliptin or sitagliptin-metformin, presence of infertility factors other than anovulation, male infertility, pelvic organic pathologies, congenital adrenal hyperplasia, thyroid dysfunction, Cushing's syndrome, hyperprolactinemia, androgen secreting neoplasia, diabetes mellitus, consumption of medications affecting carbohydrate metabolism, taking hormonal analogues other than progesterone two months prior to enrollment, and severe hepatic, Pancreatic or kidney diseases were considered as exclusion criteria.

Intervention groups
Patients divide into 4 groups (n=20): group1: metformin (500 mg two times daily),group2: Sitagliptin (50 mg two times daily), gruop3: sitagliptin-metformin (50/500 mg two times daily) and group4: placebo two times daily.

Main outcome variables
Oocyte quality, embryo quality, metabolic and hormonal factors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191127045519N1**
Registration date: **2019-12-10, 1398/09/19**
Registration timing: **retrospective**

Last update: **2019-12-10, 1398/09/19**
Update count: **0**

Registration date
2019-12-10, 1398/09/19

Registrant information

Name
Delbar Daneshjou

Name of organization / entity
Arak university

Country
Iran (Islamic Republic of)

Phone
+98 51 4335 8596

Email address
d.daneshjou@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-08-14, 1398/05/23

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study on Therapeutic Effect of Sitagliptin-Metformin and Metformin in Infertile Women with polycystic ovary syndrome (PCOS) undergoing intra-cytoplasmic sperm injection (ICSI)

Public title
A Comparative Study on Therapeutic Effect of Metformin and Sitaformin in Infertile Women with polycystic ovary syndrome (PCOS) undergoing intra-cytoplasmic sperm injection (ICSI)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
infertile Patients with polycystic Ovary Syndrome age range of 25 to 35 years
Exclusion criteria:
Age
From **25 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done from a computer-generated sequence, concealed in sequentially numbered, sealed, opaque envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
The tablets of sitagliptin, metformin, sitagliptin-metformin and placebo are placed in similar containers and given to patients by midwife. Also, the gynecologist is not aware of the type of treatment patients receive.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti university of Medical science
Street address
Shahid erabi Ave., yaman Blv., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-07-15, 1396/04/24
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.424

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
no. of Oocyte retrieved
Timepoint
once, in day of puncture
Method of measurement
Oocyte retrieval was performed by ultrasound-guided transvaginal aspiration using a single-lumen needle.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: oral rehydration salts (ORS, Poursina, Tehran, Iran) two times daily
Category
Placebo

2

Description
Intervention group 1: received Met (Glucophage, Merck, West Drayton, UK; 500 mg two times daily)
Category

Treatment - Drugs

3

Description
Intervention group2: received Sita (Januvia, Merck,West Drayton, UK. 50 mg two times daily)
Category
Treatment - Drugs

4

Description
Intervention group3: which received Sitaformin (Janumet, Merck,West Drayton, UK. 50/500 mg) two times daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh Hospital
Full name of responsible person
Delbar Daneshjou
Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
11858 17311
Phone
+98 21 5506 2628
Email
D.daneshjou@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak university
Full name of responsible person
Dr. Alireza Fazlali
Street address
Arak university, Karbala Blvd., Basij Square
City
Tehran
Province
Markazi
Postal code
۳۸۴۸۱۷۷۵۸۴
Phone
+98 86 3277 4031
Fax
Email
p-r@araku.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Arak university
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

2

Sponsor
Name of organization / entity
Infertility and Reproductive Health Research Center Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. seyyed Jalil Hoseyni
Street address
Iran, Tehran , Tajrish Sq. , Shohada-e-Tajrish Hospital
City
Tehran
Province
Tehran
Postal code
195585239515
Phone
+98 21 2271 2234
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Infertility and Reproductive Health Research Center Shahid Beheshti 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
Arak niversity

Full name of responsible person
Delbar Daneshjou

Position
PHD student

Latest degree
Master

Other areas of specialty/work
Developmental biology

Street address
No. 1, Bozorgian Ave., Madani Blvd., narmak

City
Tehran

Province
Tehran

Postal code
1955856384

Phone
+98 21 2249 2891

Email
d.daneshjou@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak university

Full name of responsible person
Delbar Daneshjou

Position
PHD student

Latest degree
Master

Other areas of specialty/work
Developmental biology

Street address
No. 1, Bozorgian Ave., Madani Blvd., narmak

City
Tehran

Province
Tehran

Postal code
1955856384

Phone
+98 21 2249 2891

Email
d.daneshjou@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
arak university

Full name of responsible person
Delbar Daneshjou

Position
PHD student

Latest degree
Master

Other areas of specialty/work
PHD student

Street address
No. 1, Bozorgian Ave., Madani Blvd., narmak

City
Tehran

Province
Tehran

Postal code
1955856384

Phone
+98 21 2249 2891

Email
D.daneshjou@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data such as metabolic factors, number of eggs, and embryos will be available.

When the data will become available and for how long
Access will start 12 months after printing.

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data will be made available for statistical analysis if all partners agree.

From where data/document is obtainable
Delbar Danesshjou Email:D.daneshjou2yahoo.com Phone number: 00989120823342

What processes are involved for a request to access data/document
Data should be extracted from patient records and made available about 2 month later.

Comments