

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of pregnancy outcomes in infertile patients with polycystic ovarian syndrome receiving Menogon monotherapy alone and in patients receiving Gonal-F and Menogon for ovulation induction in women

Protocol summary

Study aim

Determination and comparison of pregnancy outcomes in infertile patients with polycystic ovary syndrome receiving monogonal medication alone and patients receiving GonalF and Mannogan for ovulation induction in women referring to Hazrat Zahra clinic of Shahrekord in 1397

Design

Clinical trials without control group, with parallel groups, not blind, not randomized

Settings and conduct

100 infertile PCOS patients who were referred to the Infertility Clinic of Hazrat Zahra Shahrekord in 1997 and were candidates for fertility in the laboratory were selected. The age of women was less than 40 years old. Age, husband's age, duration of infertility, presence of PCOS symptoms, the result of hysterosalpingogram to reject tubal infertility, and the results of laboratory analysis of semen analysis, FSH and LH were collected by the trained midwife of the infertility center and recorded in the checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Polycystic ovary syndrome; Age younger than 40 years; Induction of in vitro fertilization; No response to treatment with clomiphene citrate in patients; Exclusion criteria: Blocking both tubes as the cause of infertility; Hypothalamic amenorrhea as the cause of infertility; Early ovarian failure as the cause of infertility; Infertility due to severe male or azoospermia; Diabetes; Thyroid problems; Kidney disease; Sensitization to letrozole and clomiphene

Intervention groups

Patients are divided into two intervention groups. The group received Monogon alone and the group receiving monogast and gonad

Main outcome variables

The number of ocits earned; Endometrial thickness;

Number of cases of empty follicular syndrome; The number of cases of ovarian hyperstimulation syndrome; Human Chorionic Gonadotropin; Fetal heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N10**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **prospective**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-02, 1398/03/12

Expected recruitment end date

2019-10-04, 1398/07/12

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of pregnancy outcomes in infertile patients with polycystic ovarian syndrome receiving Menogon monotherapy alone and in patients receiving Gonal-F and Menogon for ovulation induction in women

Public title
Effect of consumption of Gonal-F and Menogon on the fertility of infertile patients with Polycystic Ovary Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infection with polycystic ovary syndrome Age less than 40 years Induction of in vitro fertilization No response to treatment with clomiphene citrate in patients
Exclusion criteria:
Blocking both tubes as the cause of infertility Hypothalamic amenorrhea as the cause of infertility Early ovarian failure as the cause of infertility Infertility due to severe male or azoospermia Diabetes Problems with thyroid problems Kidney Disease Sensitization to letrozole and clomiphene

Age
To 40 years old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 100

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address
Vice chancellor for research, Building No. 2,
University headquarters, Ayatollah Kashani Blvd

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713492

Approval date
2019-02-03, 1397/11/14

Ethics committee reference number
IR.SKUMS.REC.1397.263

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
The number of ocits earned

Timepoint
7 and 12 days after the intervention

Method of measurement
Vaginal ultrasound

2

Description
Endometrial thickness

Timepoint
7 and 12 days after the intervention

Method of measurement
Measurement

3

Description
Number of cases of empty follicular syndrome

Timepoint
7 and 12 days after the intervention

Method of measurement
Vaginal ultrasound

4

Description
The number of cases of ovarian hyperstimulation syndrome

Timepoint

7 and 12 days after the intervention
Method of measurement
Based on the amount of free fluid in the abdomen with ultrasound

5

Description
Human Chorionic Gonadotropin
Timepoint
16 days after the transfer of embryos
Method of measurement
Experiment

6

Description
Fetal heart rate
Timepoint
6 weeks after fertilization
Method of measurement
FHR machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the first group, manogan injections containing 75 units of LH and 75 units of FSH were injected once a day and for 10-12 days.
Category
Treatment - Drugs

2

Description
Intervention group: For the second group, for ovulation stimulation, a gonadotropin-releasing hormone (GnRH)-agonist containing ampoule containing 75 units of FSH is used subcutaneously for up to 7 days or as long as the follicles reach 12 mm, then the monogonadotropin and gonadotropin-releasing hormone (GnRH) time is prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zahra clinic of Shahrekord
Full name of responsible person
Maryam Nemati
Street address
Next to the mosque of Imam Hasan, Saadi street
City
Shahrekord
Province

Chahar-Mahal-va-Bakhtiari
Postal code
8816788640
Phone
+98 38 3222 0478
Email
Mertanem@yahoo.co.uk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahrekord University of Medical Sciences
Full name of responsible person
Dr. seyed Kamal Solati (Associate Professor of Psychology)
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3334 2414
Email
kamal_solati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahrekord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Nemati
Position
Associate professor
Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Next to the mosque of Imam Hasan, Saadi street
City
Shahrekord
Province
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Postal code
8816788640
Phone
+98 38 3222 0478
Email
Mertanem@yahoo.co.uk

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Nemati
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Nemati
Position
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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

No - There is not 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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Hazrat Zahra clinic of Shahrekord

What processes are involved for a request to access data/document

After the investigation of researcher request and presentation of required documents will be accessible.

Comments