

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 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  
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## 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**  
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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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**Latest degree**

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**Other areas of specialty/work**  
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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