Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Adding Prostaglandin to Clomiphene Citrate in Mild Ovarian Stimulation Protocol in those Undergoing Intrauterine Insemination; A Randomized, Double-Blind, Clinical Trial

Protocol summary

Study aim

To determine the effects of adding prostaglandin to CC in mild ovarian stimulation protocol on pregnancy and implantation rate in patients undergoing intrauterine insemination (IUI).

Design

In this randomized, double-blind, placebo-controlled study, we will include a total number of 106 patients who will be randomized to two study groups each containing 53 patients. This is a phase 3 trial.

Settings and conduct

The study will be conducted Shiraz Ghadir Mother and Child hospital, affiliated with Shiraz University of Medical Sciences. Patients will be randomly assigned to received mild ovarian stimulation with clomiphene citrate, gonadotropins and misoprostol (intervention group) and mild ovarian stimulation with clomiphene citrate, gonadotropins and placebo (control group). All the interventionists, those recording the outcome measures and patients will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

All the patients who are candidates and refer to the Shiraz Ghadir mother and child hospital will be included in the study. All the participants must be between 18 and 45 years of age. Those with hypersensitivity to prostaglandins, polycystic ovarian syndrome (PCOS) and those with history of hepatic and renal disorders will be eliminated from the study.

Intervention groups

Study groups include mild ovarian stimulation with clomiphene citrate, gonadotropins and misoprostol (intervention group) and mild ovarian stimulation with clomiphene citrate, gonadotropins and placebo (control group).

Main outcome variables

Implantation rate, number and size of dominant ovarian follicles, endometrial thickness, pregnancy rate, side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090912002445N8**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

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Fariborz Ghaffarpasand
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Adding Prostaglandin to Clomiphene Citrate in Mild Ovarian Stimulation Protocol in those Undergoing Intrauterine Insemination; A Randomized, Double-Blind, Clinical Trial

Public title

Effects of prostaglandin and clomiphene citrate on pregnancy outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary and secondary infertility Age between 18 and 45 years Candidates for mild ovarian stimulation and intrauterine insemination (IUI)

Exclusion criteria:

Sensitivity to prostaglandins Medical history of hepatic or renal diseases Polycystic ovarian syndrome (PCOS) Not having consent for inclusion in the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **106**

Actual sample size reached: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

All the patients will be randomized into two study groups using a computer-based random digit generator utilizing the patients; registration numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications and placebo will be prepared in the same capsules. Those giving the intervention, the patients, those recording the study outcomes will be blinded to the study groups. Only the statisticians will know the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics committee office, 7th Floor, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

794-01-50-105871345-

Approval date

2016-02-12, 1394/11/23

Ethics committee reference number

IR.SUMS.MED.REC.94.01.50.10587

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.4

ICD-10 code description

Female infertility associated with male factors

Primary outcomes

1

Description

Pregnancy Rate

Timepoint

14 weeks

Method of measurement

Chemical Beta-HCG test

Secondary outcomes

1

Description

Number of Dominant Follicle

Timepoint

14 days

Method of measurement

Transvaginal Sonography

2

Description

Endometrial thinkness

Timepoint

14 days

Method of measurement
Transvaginal sonography

3

Description
Side effects
Timepoint
1 month
Method of measurement
Adverse effects form

Intervention groups

1

Description
Intervention group: Clomiphene citrate (100mg daily from day 5 to 9 of menstrual cycle), gonadotropin (75 IU subcutaneously from day 8 to 11 of menstrual cycle), misoprostol (100mg twice daily from day 5 to 9 of menstrual cycle).
Category
Treatment - Drugs

2

Description
Control group: lomiphene citrate (100mg daily from day 5 to 9 of menstrual cycle), gonadotropin (75 IU subcutaneously from day 8 to 11 of menstrual cycle), placebo (1 capsule twice daily from day 5 to 9 of menstrual cycle).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Ghadir Mother and Child Hospital
Full name of responsible person
Afsoon Zarei
Street address
Ghadir Mother and Child hospital, Emam Reza Ave.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Floor No. 7, Shiraz University of Medical Sciences, Zand Avenue
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Fax
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Email
vcrdep@sums.ac.ir
Web page address
http://research.sums.ac.ir/fa/index.html
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Pegah Keramati
Position
Fellowship resident
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
The baseline, clinical, and outcome measures databases would be available in SPSS format after publication of the study.
When the data will become available and for how long
The data will be available immediately after publication of the study.
To whom data/document is available
The data would be to the readers of the published article through the journal's policy and website.
Under which criteria data/document could be used
The is not limitation for accessing the study data after publication.
From where data/document is obtainable
The database would be available as an appendix to the published article.
What processes are involved for a request to access data/document
The database would be available as an appendix to the published article. The availability would be according to the publisher's policy.
Comments