Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effects of oxytocin and human chorionic gonadotropin in clomiphene citrate resistant polycystic ovary syndrome patients

Protocol summary

Study aim
In this study, we decided to determine the effect of oxytocin and Human Chorionic Gonadotropin(HCG) on ovulation and pregnancy.

Design
The randomized double blinded clinical trial in three groups of 42 cases with a parallel group was done.

Settings and conduct
Double blind clinical trial was performed on patients referred to infertility center of Shahid Akbar Abadi Hospital in Tehran. patients and doctors were blinded.

Participants/Inclusion and exclusion criteria
Infertile women with chronic ovulation disorder and polycystic ovarian syndrome (based on Rotterdam criteria 2003), who was treated with clomiphene citrate (150 mg) and did not pregnant, age of 19 to 45 years old, Body Mass Index of 27 to 32, at least one of the ovarian tubes with hysterosalpingography is open and no other pelvic pathology, were included in the study.. Any allergy to oxytocin and cardiovascular disease and other causes of infertility were excluded.

Intervention groups
Clomiphene citrate resistant polycystic ovary syndrome patients were studied.The volunteers with the above conditions were randomly assigned to three separate groups. In the first group, Letrozole and human chorionic gonadotropin, in the second group, Letrozole and oxytocin and in the third group, Letrozole and HCG and oxytocin were given. Letrozole (5 mg) was given since second to the fifth day of the menstrual cycle for 5 days, to grow follicles. Then, trans vaginal ultrasonography was performed on thirteenth day of menstrual cycle to measure the dominant follicle size, follicular count and endometrial thickness. In women with a follicle of 18 to 22 mm, to stimulate ovulation, 10-unit of oxytocin and or 5,000-unit HCG were injected.

Main outcome variables
Pregnancy, Abortion, Multiple pregnancy, Dominant Follicle Size, Follicle Count, Endometrial Thickness were analysed.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171031037130N2**
Registration date: **2018-05-07, 1397/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-07, 1397/02/17**
Update count: **0**

Registration date
2018-05-07, 1397/02/17

Registrant information

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Armaghan Eshraghian

Name of organization / entity
Iums

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-25, 1396/08/03

Expected recruitment end date
2018-05-22, 1397/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of oxytocin and human chorionic gonadotropin in clomiphene citrate resistant polycystic ovary syndrome patients

Public title
The effects of Oxytocin on Ovulation and Pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clomiphen citrate resistant poly cystic ovary syndrome patients 19 - 45 years old At least one ovarian tube is open in HSG Normal Semen analysis of husband No other pelvic pathology

Exclusion criteria:
Hypersensitivity to Oxytocin History of Cardio vascular disease Use of anti hypertensive drug blood pressure lower than 60/90 abnormal spermogram hyper prolactinoma anatomical disorder of uterus and tubal factor karyotype disorder

Age
From **19 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, after determining the sample size, Patients were randomly assigned to one of three groups using stratified randomization. Allocation Concealment was performed by sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, a plan was first described for the patient.The patient, the researcher and the physician did not know the group. For each treatment, the code was assigned and placed in an envelop and then put in a box, randomly.The agent who conducted the randomization process, did not engage with other steps.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway,

City
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Province
Tehran

Postal code
14665-354

Approval date
2017-10-24, 1396/08/02

Ethics committee reference number
IR.IUMS.FMD.REC 1396.9311290002

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
pregnancy percentage

Timepoint
pregnancy test and sonography after induction of ovulation

Method of measurement
serum beta HCG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Letrozole (5 mg) was given since second to the fifth day of the menstrual cycle for 5 days, to grow follicles. Then, trans vaginal ultrasonography was performed on thirteenth day of menstrual cycle to measure the dominant follicle size, follicular count and endometrial thickness. In women with a follicle of 18 to 22 mm, to stimulate ovulation, 10-unit of oxytocin were injected. Then participants were examined for pregnancy

(biochemical or clinical) and abortion and multiple pregnancies

Category

Treatment - Drugs

2

Description

Intervention group 2: Letrozole (5 mg) was given since second to the fifth day of the menstrual cycle for 5 days, to grow follicles. Then, transvaginal ultrasonography was performed on thirteenth day of menstrual cycle to measure the dominant follicle size, follicular count and endometrial thickness. In women with a follicle of 18 to 22 mm, to stimulate ovulation, 5,000-unit HCG were injected. Then participants were examined for pregnancy (biochemical or clinical) and abortion and multiple pregnancies

Category

Treatment - Drugs

3

Description

Intervention group 3: Letrozole (5 mg) was given since second to the fifth day of the menstrual cycle for 5 days, to grow follicles. Then, transvaginal ultrasonography was performed on thirteenth day of menstrual cycle to measure the dominant follicle size, follicular count and endometrial thickness. In women with a follicle of 18 to 22 mm, to stimulate ovulation, 10-unit of oxytocin and 5,000-unit HCG were injected. Then participants were examined for pregnancy (biochemical or clinical) and abortion and multiple pregnancies

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Science

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mojgan Javedani Masroor

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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