

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effect of Green tea Tablet and Placebo on ovulation induction in patients with polycystic ovary syndrome

Protocol summary

Study aim

Evaluation of the Effect of Green Tea on Ovulation Induction in Patients with Polycystic Ovary Syndrome

Design

The Randomized Controlled Clinical Trial. Groups were divided into control and case groups, each with 48 patients. One Group was treated with Placebo and the other group was treated with Green Tea and both groups received Clomiphene.

Settings and conduct

This study was performed on patients with Polycystic ovary syndrom (according to Rotterdam criteria and gynecologist approval) and infertility referred to the infertility clinic of Hamadan Fatemieh Hospital in 2019. Experimental group received 500 mg green tea capsules (to be taken twice a day for 1 weeks and then three times a day for 3 months), and then induction with clomiphene. Clomiphene was given twice daily from Day 3 of the periodic cycle for 7 days and sonography was performed on day 13 cycles. In case of dominant follicle 2 HCG 50000 was injected and coitus was scheduled and luteal phase progesterone support was given at the end of day 28 cycle. BHCG was checked and progesterone continued if positive. Control group received only placebo. After three months they received induction with clomiphene and Scheduled intercourse as in the first group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participation Satisfaction in Study, PCOS Diagnostic Criteria. Exclusion criteria: Metabolic Diseases such as: Diabetes, HTN, Cardiovascular Disease, Use of Hormonal Drugs and Drugs to Lose Weight.

Intervention groups

Intervention Group. Green Tea Capsule 500 mg Received (twice daily for one week) and then 3 times daily for three months and then subjected to induction with Clomiphene. Clomiphene is given 2 times daily from day 3 cycle for 7 days. Control group received placebo

capsule at the same period. After three months they received Induction with Clomiphene.

Main outcome variables

BHCG Titration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200213046483N1**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **retrospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Azadeh Shariatifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7683 1691

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Green tea Tablet and Placebo on ovulation induction in patients with polycystic ovary syndrome

Public title

The Effects of Green Tea Tablet in Ovulation Induction in Patients with Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participation in study PCOS diagnostic criteria

Exclusion criteria:

Have Metabolic diseases such as: Diabet, HTN, Cardiovascular disease Use Hormonal drugs and drugs to lose weight

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was done through providing drug-containing envelopes which were numbered based on random allocation table by someone outside the study. Afterwards, envelopes were handed to the doctor to give them to patients in turn. The procedure continued for patients until the desired sample size was reached.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical

Sciences

Street address

Hamadan University of Medical Sciences, in front of Mardom Park

City

Hamedan

Province

Hamadan

Postal code

6517838736

Approval date

2020-01-12, 1398/10/22

Ethics committee reference number

IR.UMSHA.REC.1398.881

Health conditions studied**1****Description of health condition studied**

Polycystic Ovary Syndrom

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Laboratory Patient Pregnancy

Timepoint

16 Weeks After Intervention

Method of measurement

Pregnancy Test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A group of people with confirmed PCOS who was in infertility and treated with green tea. The procedure was that the green tea capsule was given 500 mg (twice daily for one week) and then given 3 times daily for three months and then subjects inducted by clomiphene. Clomiphene gave 2 times daily for 7 days from days 3 cycle and sonography was performed day 13 cycles. In the case of the dominant follicle, 2 HCG 50000 injected and coitus was scheduled. Progesterone prescribed during the luteal phase. At the end of the 28th day of the cycle, the BHCG level checked and progesterone continued if it was positive.

Category

Treatment - Drugs

2

Description

Control group: placebo capsule (capsule containing flour) (2 times daily for 1 week) and then 3 times daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemye Hospital

Full name of responsible person

Dr.Soghra.Rabie

Street address

Fatemieh Hospital., Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Vice Chancellor for Research and Technology,
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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Azadeh Shariatifar

Position

Gynecology Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Azadeh Shariatifar

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Medical doctor

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

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