Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 Titrage

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

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Iran (Islamic Republic of)

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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 gived 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 be 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Saeid Bashirian
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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
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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