

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparative efficacy of Nettle (*Urtica Dioica*) with Combined Oral Contraceptive pills (COCs), on Clinical and Paraclinical Symptoms of Polycystic Ovary Syndrome (PCOS): A Triple Blind Randomized Controlled Trial

Protocol summary

Study aim

Comparing the effects of nettle extract with combined oral contraceptives (COCs) on clinical and paraclinical symptoms of polycystic ovary syndrome.

Design

controlled clinical trial, phase 3, with two-parallel groups, triple-blind

Settings and conduct

This study will be conducted in the clinics of the University of Medical Sciences and the Faculty of Traditional Medicine. The random assignment sequence will be determined by a person not involved in the study using G-Power software. To conceal the allocation of drug or placebo, it will be placed in opaque, sequentially numbered envelopes. Qualified people will be placed in two intervention and control groups using the random block method with a block size of 6 and with a 1:1 allocation sequence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 18-40 years who have been diagnosed with PCOS according to the Rotterdam criteria for the diagnosis of PCOS and are literate, do not use hormonal contraceptives and do not want to get pregnant. Exclusion criteria: relative and absolute contraindications of LD pills, undergoing infertility treatment, surgery on the ovary, sensitivity to nettle, disorders leading to hyperandrogenism.

Intervention groups

Intervention group: nettle extract capsules (containing flavonoids, tannins and sterols) in the number of 30 capsules daily for use in each cycle and control group: LD capsules (containing 30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel) in the number of 21 capsules along with 9 capsules Contains an ineffective substance for use in a 30-day cycle, which will be placed in the same package for use in three cycles separately.

Main outcome variables

Average serum level of DHEA and total testosterone;
Average score of hirsutism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110606006709N25**
Registration date: **2023-05-18, 1402/02/28**
Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **0**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-12-22, 1402/10/01 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	consecutively numbered opaque envelopes to conceal drug or placebo allocation, and prepared according to the allocation sequence by The person not involved in the research will be done from number 1 to 60.
Scientific title Comparative efficacy of Nettle (Urtica Dioica) with Combined Oral Contraceptive pills (COCs), on Clinical and Paraclinical Symptoms of Polycystic Ovary Syndrome (PCOS): A Triple Blind Randomized Controlled Trial Public title Comparing the effect of nettle extract with COCs on the improvement of clinical and paraclinical symptoms of polycystic ovary syndrome.	Blinding (investigator's opinion) Triple blinded Blinding description Medicines (nettle extract and LD) will be prepared by the pharmaceutical company in a completely similar form in terms of shape, color and smell. The participant, researcher, data analyst will be unaware of the type of intervention received.
Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Confirming the diagnosis of PCOS according to the Rotterdam criteria (clinical or biochemical hyperandrogenism, menstrual cycle disorders or polycystic ovary ultrasound signs) Age 18 to 40 years Being literate in reading and writing BMI between 18.5 and 30 Not using hormonal contraceptives or any other type of hormonal medication currently and during the last three months Not wanting to get pregnant Exclusion criteria: Relative and absolute contraindications of LD tablets (having blood pressure above 14/9, smoking and alcohol use, pregnancy or breastfeeding, alcohol and smoking use, suspicion of breast cancer, coronary heart disease, endometrial carcinoma, etc.) Women undergoing infertility treatment at the time of study. Previous surgery on one or both ovaries. Allergy to nettle Disorders that cause hyperandrogenism (having Cushing's syndrome, adrenal hyperplasia, androgen-producing tumors, etc.)	Placebo Used Assignment Parallel Other design features
Age From 18 years old to 40 years old Gender Female	Secondary Ids empty
Phase 3 Groups that have been masked - Participant - Investigator - Data analyser	Ethics committees <u>1</u>
Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized	Ethics committee Name of ethics committee Ethics Committee of Tabriz University of Medical Sciences Street address Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz City Tabriz Province East Azarbaijan Postal code 5138947977 Approval date 2023-05-09, 1402/02/19 Ethics committee reference number IR.TAZMED.REC.1402.113
Randomization description The participants will be placed in two intervention and control groups using a random block method with a block size of 6 and with a 1:1 allocation sequence. The allocation sequence will be determined by a person not involved in the study using G-Power software, placed in	Health conditions studied <u>1</u> Description of health condition studied Clinical and paraclinical symptoms of polycystic ovary syndrome ICD-10 code E28.2 ICD-10 code description Polycystic ovarian syndrome Primary outcomes <u>1</u> Description

Serum levels of DHEA and total testosterone

Timepoint

Before the start of the intervention and 3 months after the intervention

Method of measurement

By ELISA method in the central laboratory

2

Description

Average score of hirsutism

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Ferriman–Gallwey scale

Secondary outcomes

1

Description

Normalization of menstrual cycles

Timepoint

Before the intervention, one month, two months, and three months after the intervention

Method of measurement

Questionnaire made by the researcher and Higham's chart

2

Description

Serum level of fasting blood sugar

Timepoint

Before the start of the intervention and and 3 months after the intervention

Method of measurement

By spectrophotometric method in the central laboratory

3

Description

Serum levels of gonadotropins (FSH and LH)

Timepoint

Before the start of the intervention and and 3 months after the intervention

Method of measurement

By ELISA method in the central laboratory

Intervention groups

1

Description

Nettle extract capsules (containing flavonoids, tannins and sterols) in the number of 30 capsules, one daily for three cycles, which will be prepared and packaged by Sina Navandish Company.

Category

Treatment - Drugs

2

Description

Control group: LD capsules (containing 30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel), in the number of 21 capsules along with 9 capsules containing an ineffective substance to be consumed in a cycle of 30 capsules per day for three cycles, which will be prepared and packaged by Sina Navandish Company .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Faride Majdi

Street address

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

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Full name of responsible person

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Position

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Latest degree

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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