

Study Protocol with Statistical Analysis Plan and Informed Consent Form

Official Title: Evaluation of Serum Preptin Levels and Their Relationship with Insulin Resistance in Patients with Polycystic Ovary Syndrome

Acronym: PREPTIN-PCOS

ClinicalTrials.gov Identifier (NCT Number): Not yet assigned

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Sponsor: University of Health Sciences Türkiye

Study Title

Evaluation of Serum Preptin Levels and Their Relationship With Insulin Resistance in Patients With Polycystic Ovary Syndrome

Acronym

PREPTIN-PCOS

Study Design

This study is designed as a single-center prospective comparative cross-sectional observational study. The study will be conducted between June 15, 2026 and September 15, 2026 in the Internal Medicine outpatient clinic.

Study Population

The study population will consist of women aged 18–45 years presenting with complaints of hirsutism, menstrual irregularity, and hyperandrogenism.

Participants diagnosed with polycystic ovary syndrome (PCOS) according to the Rotterdam criteria will constitute the PCOS group. Women with similar clinical complaints who do not fulfill Rotterdam diagnostic criteria for PCOS will serve as the control group.

A minimum of 60 participants will be enrolled:

- PCOS group: 30 participants
- Control group: 30 participants

Study Objectives

Primary Objective

To evaluate serum preptin levels in patients with PCOS.

Secondary Objectives

- To investigate the relationship between serum preptin levels and insulin resistance.
- To evaluate associations between preptin levels and hormonal/metabolic parameters.

Study Procedures

Demographic and clinical characteristics including age, smoking status, menstrual irregularity, body weight, height, body mass index (BMI), waist circumference, and waist-to-hip ratio will be recorded.

Routine laboratory parameters obtained during standard clinical evaluation will include:

- FSH
- LH
- Estradiol
- Delta-4 androstenedione
- DHEA-SO₄
- Total testosterone
- Prolactin
- TSH
- Free T₄
- HOMA-IR

Suprapubic pelvic ultrasonography findings will also be recorded.

Additionally, one blood sample will be collected from each participant for serum preptin measurement. Samples will be centrifuged and stored at -80°C until analysis. Serum preptin levels will be analyzed using ELISA kits at Baran Medical Laboratory.

No additional fee will be charged to participants or the national insurance system.

Inclusion Criteria

1. Female participants aged 18–45 years
2. Diagnosis of PCOS according to Rotterdam criteria
3. No treatment for PCOS within the last 6 months
4. Non-pregnant and non-lactating
5. No active infection
6. No rheumatologic or inflammatory disease
7. No chronic systemic disease such as hypertension, diabetes mellitus, or chronic renal failure
8. BMI <30 kg/m²
9. Written informed consent provided

Exclusion Criteria

1. Age below 18 years or above 45 years
2. Pregnancy or breastfeeding
3. Treatment for PCOS within the last 6 months

4. Active infection
5. Rheumatologic or inflammatory disease
6. Hypertension, diabetes mellitus, chronic renal failure, or other chronic systemic disease
7. Refusal to participate in the study

Statistical Analysis Plan

Statistical analyses will be performed using SPSS version 22.0 for Windows (IBM Corporation, Chicago, IL, USA).

Continuous variables will be expressed as mean $\pm$ standard deviation, while categorical variables will be expressed as frequency and percentage.

Normality of distribution will be assessed using the Shapiro-Wilk test.

For comparisons between two groups:

- Independent Samples t-test will be used for normally distributed variables.
- Mann–Whitney U test will be used for non-normally distributed variables.

For comparisons involving more than two groups:

- One-Way ANOVA test will be used for normally distributed variables.
- Kruskal–Wallis test will be used for non-normally distributed variables.

Categorical variables will be compared using the Chi-square test.

Correlation analyses:

- Pearson correlation analysis will be used for normally distributed variables.
- Spearman correlation analysis will be used for non-normally distributed variables.

Multivariate regression analysis will be performed to identify independent associations between serum preptin levels and clinical/metabolic parameters.

A p-value <0.05 will be considered statistically significant.

Risks and Benefits

The study involves minimal risk. Participants will undergo routine clinical evaluations, and only one additional blood sample will be collected for serum preptin analysis.

The findings may contribute to better understanding of the role of preptin in the pathophysiology of PCOS and its relationship with insulin resistance.

Informed Consent Form

Participant Information and Consent

You are invited to participate in a research study investigating serum preptin levels in patients with polycystic ovary syndrome (PCOS). Participation in this study is entirely voluntary.

If you agree to participate:

- Your demographic and clinical data will be recorded.
- One additional blood sample will be collected for serum preptin analysis.
- No additional payment or cost will be required.

Your participation or refusal will not affect your medical care in any way.

All personal information obtained during the study will remain confidential and will be used only for scientific purposes.

You may withdraw from the study at any time without providing any reason.

By signing this form, you confirm that:

- You have read and understood the study information.
- You voluntarily agree to participate in the study.

Participant Name-Surname: _____

Signature: _____

Date: _____

Researcher Name-Surname: _____

Signature: _____