INFORMED CONSENT FORM

For Participation in an Observational Clinical Study

Official Title	Hormonal Normalization Is Not Metabolic Recovery: Adipokine Dynamics After Levothyroxine Replacement in Newly Diagnosed Primary Hypothyroidism
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Study Site	University of Health Sciences, Basaksehir Cam and Sakura City Hospital

Please read this form carefully. You may ask any questions before deciding whether to participate. Participation is voluntary.

1. Invitation and Purpose of the Study

You are being invited to participate in a prospective observational study because you have been newly diagnosed with primary hypothyroidism and have not previously received thyroid hormone replacement therapy. The purpose of this study is to evaluate how serum adipokine levels and metabolic parameters change after 8 weeks of standard-of-care levothyroxine treatment. The study focuses on four adipokines: asprosin, adipolin, omentin-1, and visfatin.

2. Why Is This Study Being Conducted?

Hypothyroidism can affect lipid metabolism, glucose-insulin balance, body composition, liver-related metabolic indices, and adipose tissue function. Levothyroxine treatment usually improves thyroid hormone levels; however, metabolic recovery may not occur at the same pace as biochemical thyroid recovery. This study aims to better understand the relationship between thyroid-axis recovery, adipokine dynamics, and metabolic remodeling.

3. Study Design

This is a single-center, prospective observational cohort study. No experimental drug or investigational device will be used. Levothyroxine treatment will be prescribed as part of routine clinical care according to the decision of the treating physician. The study will compare measurements obtained before treatment initiation with measurements obtained after 8 weeks of therapy.

4. What Will Happen If You Participate?

If you agree to participate, your clinical and laboratory data will be collected at baseline and at the 8-week follow-up visit. Fasting blood samples will be obtained in the morning. Routine tests may include thyroid function tests, lipid profile, glucose, insulin, liver enzymes, kidney function markers, inflammatory markers, and other routine biochemical parameters. Additional serum samples will be used to measure adipokines including asprosin, adipolin, omentin-1, and visfatin. Anthropometric measurements such as body weight, height, body mass index, and waist circumference may also be recorded.

5. Biospecimen Collection and Storage

Venous blood samples will be collected after overnight fasting. Serum samples will be processed according to the study protocol and stored at -80°C until adipokine and metabolic biomarker analyses are performed. The retained samples will be serum samples without planned DNA extraction or genetic analysis. Samples will be used only for analyses related to the aims of this study and in accordance with ethics committee approval.

6. Possible Risks and Discomforts

The main study-related risk is related to venous blood sampling, which may cause temporary pain, bruising, mild bleeding, dizziness, or rarely infection at the puncture site. Levothyroxine treatment is not experimental in this study and will be given as standard clinical care. Any treatment-related medical decisions will be made by your physician.

7. Possible Benefits

You may not receive a direct personal benefit from participation. However, the study may help improve scientific understanding of metabolic and adipokine-related changes during levothyroxine treatment in newly diagnosed primary hypothyroidism.

8. Voluntary Participation and Right to Withdraw

Participation in this study is completely voluntary. You may refuse to participate or withdraw from the study at any time without giving a reason. Refusing to participate or withdrawing from the study will not affect your medical care, relationship with your physicians, or access to standard treatment.

9. Confidentiality and Data Protection

Your personal and medical information will be kept confidential. Study data will be coded and stored securely. Only authorized study personnel and relevant regulatory or ethics bodies, when necessary, may access study records. Results may be published or presented scientifically, but you will not be personally identified in any report or publication.

10. Costs and Compensation

There will be no additional cost to you for participating in this study. No payment or financial compensation is planned for participation.

11. Alternatives to Participation

Your alternative is not to participate in the study. You will still receive standard clinical evaluation and treatment for hypothyroidism.

12. Contact Information

If you have questions about the study, your rights as a participant, or study-related procedures, you may contact the study team at the Internal Medicine Department of University of Health Sciences, Basaksehir Cam and Sakura City Hospital. Contact details should be completed by the study team before use of this form.

13. Consent Statement

I have read and understood the information provided in this informed consent form. I have had the opportunity to ask questions, and my questions have been answered satisfactorily. I understand that participation is voluntary and that I may withdraw at any time without affecting my medical care. By signing below, I voluntarily agree to participate in this study.

Signatures

Role	Name and Surname	Date / Signature
Participant		
Person Obtaining Consent		
Witness, if applicable		
Legal Representative, if applicable		

Version note: This document contains no names of research participants and is intended for public ClinicalTrials.gov document upload after PRS review, if required.