Study Protocol with Statistical Analysis Plan and Informed Consent Form

Official Study Title: Evaluation of Serum Irisin Levels in Patients With Diabetic Polyneuropathy

NCT Number: (To be assigned by ClinicalTrials.gov)

Protocol Version Date: 30.06.2026

Background and Rationale

Diabetic peripheral neuropathy (DPN) is one of the most common microvascular complications of Type 2 Diabetes Mellitus and is associated with impaired balance, gait abnormalities, increased fall risk, and decreased quality of life. Irisin is a myokine secreted by skeletal muscle and is associated with metabolic regulation, insulin sensitivity, and anti-inflammatory effects.

This study aims to investigate serum Irisin levels in diabetic patients with and without polyneuropathy and evaluate their relationship with metabolic and clinical parameters.

Study Objectives

Primary Objective:
To evaluate serum Irisin levels in diabetic patients with diabetic polyneuropathy.

Secondary Objectives:
- To compare serum Irisin levels between diabetic patients with and without neuropathy and healthy controls
- To investigate associations between Irisin levels, HbA1c, and fasting plasma glucose
- To evaluate the relationship between Irisin and diabetic peripheral neuropathy severity

Study Design

This study is designed as a single-center, analytical, observational, prospective cross-sectional study conducted between 30.06.2026 and 30.09.2026.

Participants will be divided into three groups:
1. DPN+ Group: Diabetic patients with polyneuropathy
2. DPN- Group: Diabetic patients without neuropathy
3. Healthy Control Group: Individuals without diabetes or neuropathy

Study Population

A total of 81 participants aged between 30 and 75 years will be included in the study.

Eligibility Criteria

Inclusion Criteria:
- Age between 30 and 75 years
- At least one-year history of Type 2 Diabetes Mellitus
- Ability to provide written informed consent

Exclusion Criteria:
- Vitamin B12 deficiency
- Chronic alcohol use
- Chemotherapy-related neuropathy
- Chronic kidney disease (eGFR <60 ml/min/1.73 m^2)
- Active infection
- Myopathies
- Central nervous system diseases
- Severe orthopedic disorders affecting mobility

Study Procedures

Serum Irisin levels, HbA1c, and fasting plasma glucose values will be evaluated. One peripheral venous blood sample will be collected from each participant. Blood samples will be centrifuged at 2000 rpm and stored at -80°C until analysis.

Outcome Measures

Primary Outcome:
Serum Irisin levels in diabetic patients with polyneuropathy.

Secondary Outcomes:
- HbA1c
- Fasting plasma glucose
- Relationship between Irisin and neuropathy status

Statistical Analysis Plan

Statistical analyses will be performed using SPSS software. Continuous variables will be presented as mean ± standard deviation and categorical variables as numbers and percentages.

Appropriate statistical tests including Student's t-test, Mann-Whitney U test, ANOVA, chi-square test, Pearson correlation, and Spearman correlation analyses will be used. A p-value <0.05 will be considered statistically significant.

Ethical Considerations

Written informed consent will be obtained from all participants prior to enrollment. The study protocol has been approved by the local ethics committee.

Data Sharing Statement

Individual participant data will not be publicly shared. Only anonymized aggregated data will be used in scientific publications and presentations.

Informed Consent Form

You are invited to participate in a scientific research study investigating serum Irisin levels in diabetic peripheral neuropathy.

Purpose of the Study:
The aim of this study is to evaluate the relationship between serum Irisin levels and diabetic peripheral neuropathy.

Procedures:
If you agree to participate, your clinical and laboratory findings will be recorded and one blood sample will be collected for Irisin analysis.

Risks and Benefits:
No major risk is expected apart from mild discomfort during blood collection.

Confidentiality:
All personal information will remain confidential.

Voluntary Participation:
Participation is voluntary and you may withdraw at any time.

Participant Name:
Signature:
Date:

Researcher Name:
Signature:
Date: