

Study Protocol with Statistical Analysis Plan

Official Title

Levels of DEL-1 and IL-17 in the Aqueous Humor of Cataract Patients with Diabetes without Diabetic Retinopathy

ClinicalTrials.gov Identifier

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1. Background and Rationale

Diabetic cataract is a common ocular complication of diabetes mellitus. Inflammatory mechanisms may contribute to alterations in the intraocular microenvironment before the development of diabetic retinopathy. Interleukin-17 (IL-17) is a pro-inflammatory cytokine, whereas developmental endothelial locus-1 (DEL-1) is an anti-inflammatory glycoprotein that may regulate inflammatory responses.

2. Objectives

Primary Objective

To compare aqueous humor DEL-1 and IL-17 concentrations between diabetic cataract patients without diabetic retinopathy and non-diabetic cataract controls.

Secondary Objectives

- To evaluate the association between aqueous humor DEL-1 and IL-17 concentrations.
- To evaluate the association of aqueous humor biomarker levels with HbA1c.
- To evaluate the association between demographic variables (age) and aqueous humor DEL-1 and IL-17 concentrations.
- To compare HbA1c levels between study groups.
- To evaluate the DEL-1/IL-17 ratio between study groups.

3. Study Design

Prospective, cross-sectional, observational case-control study.

Study Site: Department of Ophthalmology, Usak University Training and Research Hospital.

Participants: 61 participants (Diabetic Cataract Group, n=33; Control Group, n=28).

4. Procedures

All participants underwent comprehensive ophthalmic examination. During cataract surgery, 0.1-0.2 mL aqueous humor samples were collected under sterile conditions for biomarker analysis.

5. Outcome Measures

Primary Outcome

Difference in aqueous humor DEL-1 and IL-17 concentrations between diabetic cataract patients and non-diabetic controls.

Secondary Outcomes

1. Association between aqueous humor DEL-1 and IL-17 concentrations.
2. Association of aqueous humor DEL-1 and IL-17 concentrations with HbA1c.
3. Association between demographic variables (age) and aqueous humor DEL-1 and IL-17 concentrations.
4. HbA1c levels in diabetic cataract patients and non-diabetic controls.
5. DEL-1/IL-17 ratio.

6. Statistical Analysis Plan

Statistical analyses were performed using NCSS 2007 software. Continuous variables were summarized as mean $\pm$ standard deviation or median (interquartile range). Normality was assessed using the Shapiro-Wilk test. Mann-Whitney U test was used for between-group comparisons. Chi-square test was used for categorical variables. Spearman correlation analysis was performed separately for each study arm. Correlation coefficients (Spearman's rho) are reported separately for the Diabetic Cataract Group and the Control Group. A two-sided p value <0.05 was considered statistically significant.

7. Ethical Considerations

The study was approved by the Usak University Clinical Research Ethics Committee. Written informed consent was obtained from all participants before enrollment.