Official Title: Fundus Finding and Thiol-Disulfide Homeostasis in Gestational Diabetes

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Study Protocol

This is a prospective case-control study conducted in 26 pregnant patients diagnosed with impaired glucose status (gest DM, IGT, high 50 gr GTT level) at 24-28 weeks of pregnancy and 34 healthy pregnant women with normal glucose status in the Uşak Training and Research Hospital Gynecology and Ophthalmology clinic.

A total of 60 pregnant women participated in the study. (26 gestational diabetes and 34 healthy pregnant women). Investigators excluded patients with type 1diabetes mellitus and type 2 diabetes mellitus, patient that history of ocular surface disease, topical/systemic medical therapy,with ocular inflamatuar disease such as üveitis. The patients who is healthy pregnant and gestasional diabetes mellitus pregnant were recruit to this study. Controls group included only healthy pregnant.

All patients underwent a comprehensive ophthalmologic examination that included best-corrected visual acuity, slit-lamp examination, dilated fundus examination and applanation tonometry. Optic nerve retinal nerve fiber thickness and macular thickness were measured with OCT device in all patients

Tears analysis is less invasive, safe and accaptable method for research. Tear samples, Schirmer paper strips were placed in the lower conjunctival fornix of the right eye for a maximum of 5 minutes. Care was taken not to use tear stimulation, topical anesthetic or other eye drops. Attention was paid to factors such as lighting and room temperature. The ocular surface was not damaged. Tear samples were collected by a single individual (SD). A 15-20 mm test result was considered as enough for biochemical analysis. Schirmer strips were diluted with 500 µl previously cooled PBS (phosphate-buffered saline), and stored in Eppendorf tubes until analysis (−80 °C).

At the end of the study, fundus findings and tear oxidative stress values of both groups will be compared. ELISA method will be used for determination of tear oxidative stress findings.

The study followed the tenets of the declaration of Helsinki and was approved by the Uşak üniversitesi Ethics Committee (13.04.2023 / 93-93-04). Written and informed con-sent of participants was obtained for each patient prior to the study.