Analysis of the Diagnostic Value and Quadrant Characteristics of Iris OCTA Quantitative Blood Flow in Neovascular Glaucoma Secondary to Type 2 Diabetes Mellitus

Informed Consent Form for Participants | Version: V1.0 | Date: 2026.05.23

Dear Participant,

You are welcome to consider participating in this clinical study. This informed consent form elaborates key information regarding the study, including the research objectives, procedures, potential risks and discomforts, available benefits, personal rights, and confidentiality principles. Please read this document carefully and fully understand the contents before making an independent decision on study participation. You will be granted sufficient time for inquiry and consideration, and the research team will answer all your questions patiently. Your voluntary participation and informed choice will be fully respected.

This study strictly complies with the *Declaration of Helsinki* and relevant ethical management regulations for clinical research in China. It has been reviewed by the Ethics Committee, and your personal safety, health and legitimate rights and interests will be fully protected throughout the study.

I. Basic Study Information

Study Title: Clinical Study on Evaluating Iris Microcirculation Characteristics in Type 2 Diabetic Patients with Different Disease Courses Using Optical Coherence Tomography Angiography (OCTA)

Lead Institution: Qilu Hospital of Shandong University

Principal Investigator & Contact: Zhang Yuting, 18560088152

Study Implementers: Professionally trained ophthalmologists and specialized examination technicians

Ethics Review Committee & Contact: Research Ethics Committee of Qilu Hospital of Shandong University, 0531-82165409

II. Research Background and Objectives

Type 2 diabetes mellitus (T2DM) is a highly prevalent chronic disease in China. Ocular microcirculation injury is the core cause of irreversible blinding complications such as diabetic retinopathy and neovascular glaucoma. Iris microcirculation abnormalities occur prior to clinically visible ocular lesions, serving as a key target for early warning of diabetic ocular complications. Current targeted studies on iris microcirculation in diabetic patients remain limited. **This is a non-interventional observational study** that will not alter your routine diagnosis and treatment regimen. Based on non-invasive ocular examinations and basic clinical data, we aim to analyze the iris microcirculation characteristics of T2DM patients at different disease stages, supplement clinical research evidence, and provide non-invasive imaging references for early warning, progression monitoring, and individualized diagnosis and treatment optimization of diabetic ocular complications.

III. Study Participants and Participation Procedures

(I) Inclusion and Exclusion Overview

This study enrolls T2DM patients and healthy control participants. Individuals with severe ocular damage, inability to cooperate with ocular examinations, or relevant allergic history will be excluded. Researchers will conduct a baseline assessment before enrollment to verify your eligibility for participation.

(II) Specific Participation Procedures

1. Informed Disclosure: Researchers will fully explain the contents of this informed consent form and answer all your questions. You may sign the form voluntarily after confirming no objections.

2. Data Collection: With your consent, basic clinical information will be collected, including age, gender, diabetic duration, blood glucose control status, and previous ocular disease history. All data will be used solely for research analysis without personal privacy disclosure.

3. Non-invasive Ocular Examination: You will receive routine ophthalmic examinations and optical coherence tomography angiography (OCTA). The entire procedure is non-invasive, radiation-free, and drug-free. You only need to keep your head stable and fixate on the target light for 5–10 minutes per examination.

4. Study Completion: All study procedures will be completed once the examinations are finished, with no further routine follow-up required. The research team will conduct follow-up observation if any transient discomfort occurs until symptom relief.

IV. Potential Risks and Discomforts

This is a purely observational study with no experimental interventions, investigational drugs, invasive operations, or changes to your routine treatment. The overall risk is extremely low. Only rare mild and transient discomforts may occur without organic damage or long-term adverse effects, which are specified as follows:

(I) Transient ocular discomfort: A small number of participants with sensitive ocular surfaces, insufficient tear secretion, or poor cooperation may experience temporary dry eyes, foreign body sensation, mild soreness and distension, blurred vision or blepharospasm, which can resolve spontaneously in a short time.

(II) Mild ocular congestion: Rare participants may develop transient mild eyelid or conjunctival redness due to reduced blinking and fixed head posture during examination, with no risk of infection or tissue damage.

(III) Mild skin contact reaction: Rare participants allergic to medical alcohol may develop temporary local skin redness and itching due to residual disinfectant on equipment contact areas.

(IV) Mild systemic discomfort: A small number of participants with unstable blood glucose or sensitive vestibular function may experience transient dizziness and nausea, which can be quickly relieved after rest.

(V) Mild psychological fluctuation: Some participants may have temporary anxiety or tension after learning about their ocular conditions, without severe psychological impacts.

V. Countermeasures for Adverse Reactions and Discomforts

The research team has established a comprehensive full-process management plan to ensure your safety with standardized interventions for all possible mild discomforts:

(I) Pre-examination prevention: We will inquire about your allergic history, ocular disease history and blood glucose control status in advance. Preservative-free artificial tears will be provided for participants with dry eyes; alcohol-free disinfection will be adopted for alcohol-allergic participants; psychological counseling will be performed to reduce pre-examination tension and minimize potential discomfort risks.

(II) Instant intervention: The examination will be terminated immediately once any discomfort occurs. Targeted symptomatic management will be provided, including artificial tears for dry eyes, supine rest for dizziness, and normal saline wiping for skin allergy. All symptoms are transient and can be fully relieved within minutes to one hour in most cases.

(III) Continuous follow-up: Persistent symptoms will be evaluated and managed promptly by professional ophthalmologists, with multidisciplinary assistance if necessary. Continuous follow-up will be conducted until complete symptom resolution, and all intervention procedures will be fully documented.

VI. Benefits for Study Participants

(I) Free specialized ocular OCTA examination and routine ophthalmic assessment, enabling you to fully understand your ocular microcirculation and fundus status, detect potential early diabetic ocular lesions, and provide references for subsequent clinical diagnosis and treatment.

(II) Your participation will provide valuable clinical data for early warning and clinical research of diabetic ocular complications, helping reduce the risk of blinding complications in diabetic patients and delivering important clinical research value.

(III) You will receive one-on-one professional ophthalmic health guidance and systematic knowledge of diabetic ocular care during the study.

VII. Confidentiality of Personal Information and Research Data

(I) All your personal identity information (name, age, T2DM disease status, etc.), clinical data and examination results will be strictly confidential, used only for this research, and never applied to commercial or non-research purposes.

(II) All research data will be coded with personal identifiers removed before statistical analysis. No identifiable personal information will be disclosed in any study publications or academic exchanges.

(III) Only research team members, the Ethics Committee and relevant regulatory authorities may access your data for official work, with all access activities participant to strict confidentiality regulations.

VIII. Voluntary Participation and Right of Free Withdrawal

(I) Voluntary participation: Your participation in this study is completely voluntary. You may refuse to participate or withdraw from the study unconditionally at any stage before or during the research without any reason or explanation.

(II) No adverse impact of withdrawal: Refusal to participate or mid-study withdrawal will not affect your doctor-patient relationship, subsequent routine diagnosis, treatment, medication or any medical services, and you will not receive any unfair treatment.

(III) Withdrawal management: The research team will terminate all study-related operations immediately upon your withdrawal request. The anonymized data collected from you will be destroyed or retained for research use according to your explicit choice.。

IX. Other Important Notes

(I) All study-related examinations are free of charge, and no fees will be charged to you during the entire research period.

(II) In case of any study-related unexpected adverse events, the research team will provide free medical treatment and fully guarantee your physical health.

(III) This informed consent form is made in duplicate, with one copy retained by the participant and one by the lead institution, both with equal validity.

X. Informed Consent Confirmation

I have carefully read and fully understood all contents of this informed consent form. All my questions have been patiently answered by the research staff. I clearly acknowledge the study objectives, procedures, potential risks and discomforts, personal rights and confidentiality principles. I voluntarily participate in this quantitative study on iris microcirculation in T2DM patients, agree to complete relevant examinations and data collection in accordance with study procedures, and confirm my right to withdraw from the study unconditionally at any time.

Signature of Participant: _____

Signature of Legal Guardian (for participants without full capacity for civil conduct): _____

Signature of Authorized Agent (if applicable): _____ Date: _____

Signature of Research Staff (confirming full informed disclosure): _____ Date: _____