

Multidimensional assessment of ocular phenotypes across distinct subtypes of type 2 diabetes mellitus in a Chinese cohort

Submission date 19/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/02/2025	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 21/02/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The incidence of diabetes mellitus is rapidly increasing, and this condition often results in significant metabolic disease and severe complications. At the same time, diabetes mellitus is a highly heterogeneous disease in which the eye serves not only as an end-organ target but also as a window to systemic damage. Recent advancements in ophthalmology have provided novel tools for systemic disease stratification. This research aims to assess the 5- and 10-year risks of diabetic retinal and systemic complications (e.g., cardiovascular events, nephropathy) using ophthalmology and to identify distinct subtypes of diabetes in Chinese patients, which is helpful in understanding how these subtypes differ in long-term risks of eye damage and other health complications. The results could help doctors personalize diabetes care by using eye scans to catch complications earlier and tailor treatments to individual risks.

Who can participate?

Adults with type 2 diabetes mellitus were enrolled based on primary care-based diabetes management plans in township health centers, Shaoguan City (the part of a nationwide community screening program under China's Basic Public Health Service framework). For external validation, a parallel rural cohort from Yangxi County was included.

What does the study involve?

Eligible participants were those who completed 3 consecutive annual screenings and undergo standardized diabetic retinal examinations (e.g., administered structured face-to-face questionnaires, slit-lamp biomicroscopy and digital fundus photography). All the exams follow the normal clinical operation.

What are the possible benefits and risks of participating?

Participants benefit from receiving ocular and general tests for 3 consecutive annual screenings. No additional risks are anticipated as all the exams follow the normal clinical operation.

Where is the study run from?

Shaoguan City, Guangdong Province, China

When is the study starting and how long is it expected to run for?
January 2020 to March 2030

Who is funding the study?
National Natural Science Foundation of China

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Oculomics-Driven Identification of Diabetes Subgroups in Chinese Cohorts (ODISC)

Acronym
ODISC

Study objectives

Diabetes mellitus is a highly heterogeneous disease in which the eye serves not only as an end-organ target but also as a window to systemic damage. Recent advancements in ophthalmics have provided novel tools for systemic disease stratification. Distinct diabetic subtypes exhibit different ocular manifestations, and we hypothesize that ophthalmics can capture these subtype-specific differences.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/03/2021, Ethics Committee of Zhongshan Ophthalmic Center (No. 7 Jinsui Rd, Guangzhou, 510060, China; +86 20-66610729; zocrc@gzzoc.com), ref: 2020KYPJ160

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Individuals with diabetes

Interventions

The ODISC study is a observational cohort study that includes type 2 diabetes mellitus (T2DM) patients from a part of a nationwide community screening program under China's Basic Public Health Service framework enrolled in primary care-based diabetes management plans in Shaoguan City. Eligible participants were those who undergo standardized diabetic retinal examinations and completed three consecutive annual screenings. For external validation, a parallel rural cohort from Yangxi County was included. The examinations include: face-to-face questionnaire surveys (e.g., sociodemographic data such as age, sex, income, education; lifestyle factors such as smoking, alcohol use, physical activity; medical history and medication adherence), health data such as blood sugar levels, kidney function, and heart health; and ophthalmic evaluation (slit-lamp biomicroscopy and digital fundus photography). The study leverages artificial intelligence (AI)-driven computational methods to extract quantitative features from digital fundus photography, forming the basis of ophthalmics profiling. A deep learning framework, utilizing a pre-trained convolutional neural network (CNN) architecture (e.g., ResNet-50), was employed to automatically segment retinal vasculature, detect microaneurysms, and quantify optic disc morphology, generating 512-dimensional feature vectors for each participant. These ophthalmics parameters were then integrated into a multimodal dimensionality reduction pipeline.

Intervention Type

Other

Primary outcome(s)

The 5- and 10-year risks of diabetic retinal and systemic complications (e.g., cardiovascular events, nephropathy) are predicted using ophthalmics mainly extracted by digital fundus photography and other clinical data (at baseline, 1-year visit, 2 year-visit, 3-year visit).

Key secondary outcome(s)

The distinct diabetic subtypes were identified based on retinal phenotypic patterns. DDRTree (Discriminative Dimensionality Reduction via Learning a Tree) will be applied to project high-dimensional oculomics data into a low-dimensional latent space while preserving pseudotemporal trajectory patterns. Unsupervised clustering algorithms—including k-means (hard clustering) and Gaussian mixture models (soft clustering) are also applied.

Completion date

08/03/2030

Eligibility

Key inclusion criteria

1. Individuals aged over 18 years.
2. T2DM diagnosis was confirmed by primary care physicians using internationally accepted thresholds: fasting plasma glucose (FPG) ≥ 7.0 mmol/L, 2-hour postprandial glucose (2h-PG) ≥ 11.1 mmol/L during a 75-g oral glucose tolerance test (OGTT), or hemoglobin A1c (HbA1c) $\geq 6.5\%$.

Participant type(s)

Resident

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with type 1 diabetes, gestational diabetes, severe comorbidities (e.g., advanced cardiovascular disease like stage III-IV cardiovascular disease, chronic kidney disease with eGFR < 30 mL/min/1.73 m², or active malignancy, etc.
2. Inability to complete ophthalmic assessments.
3. Unable to give their own informed consent.

Date of first enrolment

09/03/2021

Date of final enrolment

08/09/2021

Locations

Countries of recruitment

China

Study participating centre
Shaoguan township health centers
Shaoguan
China
512000

Sponsor information

Organisation

State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

Not be shared according to legislation.

IPD sharing plan summary

Not expected to be made available