ISRCTN15557580 https://doi.org/10.1186/ISRCTN15557580

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

Registration date
21/02/2025

Overall study status
Ongoing

Last Edited
21/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 oculomics 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 oculomics 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 frame work). 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?
Dr Wei Wang, wangwei@gzzoc.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Wei Wang

ORCID ID
https://orcid.org/0000-0002-5273-3332

Contact details
No. 7 Jinsui Rd
No. 54 Xianlie South Rd
Guangzhou
China
510060
+86 15915719579
wangwei@gzzoc.com

Additional identifiers

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 oculomics have provided novel tools for systemic disease stratification. Distinct diabetic subtypes exhibit different ocular manifestations, and we hypothesize that oculomics 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; zoccrc@gzzoc.com), ref: 2020KYPJ160

Primary study design
Observational

Study design
Observational cohort study

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 oculomics 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 oculomics 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 oculomics 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) ≥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 m^2, 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 Wěiyuánhuì, , 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