

# Determinants of the onset and progression of diabetic retinopathy in south China: Guangzhou Diabetic Eye Study

<b>Submission date</b> 20/03/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/07/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diabetic retinopathy is a diabetes complication that affects the eyes. The incidence and risk factors for diabetic retinopathy in southern China remain unclear. This study aims to explore the onset and progression of diabetic retinopathy and its determinants in South China.

### Who can participate?

Type 2 diabetic patients registered in community health centres in Yuexiu district in Guangzhou, China

### What does the study involve?

Comprehensive eye tests are performed annually for 5 years, as well as blood and urine tests.

### What are the possible benefits and risks of participating?

Participants receive an annual comprehensive eye test and one-on-one ophthalmologist consultation based on the exam results. All the exams follow the normal clinical operation.

### Where is the study run from?

Zhongshan Ophthalmic Center, Sun Yat-sen University (China)

### When is the study starting and how long is it expected to run for?

November 2017 to October 2025

### Who is funding the study?

National Natural Science Foundation of China

### Who is the main contact?

Prof. Wenyong Huang  
hweny@mail.sysu.edu.cn

## Contact information

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Scientific

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## Additional identifiers

**Protocol serial number**

NOPE-2019-0244.R1

## Study information

**Scientific Title**

Guangzhou Diabetic Eye Study (GDES): exploring the onset and progression of diabetic retinopathy and the determinants in south China: a prospective cohort study

**Acronym**

GDES

**Study objectives**

This project aims to explore the onset and progression of diabetic retinopathy (DR) and their determinants through a prospective cohort in South China.

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 25/10/2017, Zhongshan Ophthalmic Center Ethics Committee, Sun Yat-sen University (No.7 Jinsui Road, Zhujiang New Town, Guangzhou, China; +86 (0)20 87332529; zocethics@163.com), ref: 2017KYPJ094

### **Primary study design**

Observational

### **Study design**

Community-based prospective cohort study

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Diabetic retinopathy screening among people with diabetes

### **Interventions**

The GDES is an ongoing community-based prospective cohort study that includes type 2 diabetic patients registered in the community health centres in Yuexiu district in Guangzhou. This district is one of the oldest and central areas of Guangzhou, the population is stable. The Zhongshan ophthalmic centre (ZOC), which is affiliated with Sun Yat-sen University in Guangzhou, is located in this district and is the main provider of eye health services for the city. The communities are stable and the community health centres have established long-term collaboration with ZOC and are fully equipped with a well-established registry system for diabetic patients. The participants were originally recruited in November 2017, and the plan was to follow up on them annually for 5 years. All ocular examinations were performed at ZOC. The examinations are as follows:

1. Visual acuity and refraction tests performed by qualified optometrists
2. Ocular biometric measurements
3. Intraocular pressure (IOP) measurement
4. Pupil dilation
5. Refraction
6. Slit lamp and fundus examinations
7. Colour retinal photographs
8. Optical coherence tomography (OCT)
9. Questionnaire interview
10. Biological sample collection

### **Intervention Type**

Other

### **Primary outcome(s)**

Prevalence, incidence and progression rates of DR, measured using grading of OCT results annually for 5 years

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

31/10/2025

## Eligibility

### Key inclusion criteria

1. Aged 35–85 years
2. Diagnosed type 2 diabetes confirmed by medical records from endocrinologists, insulin treatments, oral medicine, fasting blood glucose  $\geq 7.0$  mmol/L for at least two consecutive measurements or postprandial blood glucose  $\geq 11.1$  mmol/L
3. Ocular-treatment-naïve eyes

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

35 Years

### Upper age limit

85 Years

### Sex

All

### Key exclusion criteria

1. Any severe systemic disease, such as ischemic heart disease, stroke, cancer and kidney disease, or a history of systemic surgery, such as cardiac bypass, thrombolysis and kidney transplantation
2. Any cognitive disorder, mental disorder or failure to finish the questionnaire and all the examinations
3. Combined glaucoma, age-related macular degeneration, glaucoma, vitreous macular disease (vitreous haemorrhage, retinal detachment), amblyopia and other eye diseases
4. A history of intraocular surgery, such as retinal laser, intraocular anti-VEGF injection, glaucoma surgery, cataract surgery, laser myopia surgery and vitreoretinal surgery history
5. A failure of mydriasis due to corneal ulcer, severe refractive media turbidity or shallow anterior chamber and angle closure glaucoma

### Date of first enrolment

01/11/2017

### Date of final enrolment

31/10/2022

## Locations

### Countries of recruitment

China

**Study participating centre**  
**Zhongshan Ophthalmic Center**  
Sun Yat-sen University  
No. 54 Xianlie Nan Road  
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510000

## Sponsor information

**Organisation**  
Sun Yat-sen University

**ROR**  
<https://ror.org/0064kty71>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Sun Yat-sen University

**Alternative Name(s)**  
National Guangdong University, , , SYSU

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
China

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Wenyong Huang (hweny@mail.sysu.edu.cn). Informed consent will be obtained before the participant join the study. The study will follow the legal restrictions of the Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-sen University. For access to the data, please contact the principal investigator after the study completes.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		26/05/2025	27/05/2025	Yes	No
<a href="#">Results article</a>		01/07/2025	02/07/2025	Yes	No