ISRCTN15853192 https://doi.org/10.1186/ISRCTN15853192

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

Submission date	Recruitment status	[_] Prospectively registered
20/03/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2020	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2025	Eye Diseases	

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

Type(s)
Scientific

Contact name
Dr Wei Wang

Contact details
No. 54. Xianlie Nan Road
Yuexiu District
Guanghzou
China
510000
+86 (0)20 87334687
wangwei@gzzoc.com

Type(s)
Scientific

Contact name
Ms Yuting Li

Contact details
No. 54. Xianlie Nan Road
Yuexiu District
Guangzhou
China
510000
+86 (0)20 87334687
liyuting@gzzoc.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Community-based prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/11/2017

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 ≥7.0 mmol/L for at least two consecutive measurements or postprandial blood glucose ≥11.1 mmol/L
3. Ocular-treatment-naïve eyes

Participant type(s)
Patient

Age group
Adult

Lower age limit
35 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
1185

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
Yuexiu District
Guangzhou
China
510000

Sponsor information

Organisation
Sun Yat-sen University

Sponsor details
Zhongshan Ophthalmic Center
No. 54. Xianlie Nan Road
Yuexiu District
Guangzhou
China

510000
+86 (0)20 87334687
huangwenyong@gzzoc.com

Sponsor type
University/education

Website
http://www.gzzoc.com/

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
University/education

Funder Name
Sun Yat-sen University

Alternative Name(s)
SYSU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
The results of the study will be presented as scientific article.

Intention to publish date
31/10/2026

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?
Results article		26/05/2025	27/05/2025	Yes	No
Results article		01/07/2025	02/07/2025	Yes	No