

Exploring the Landscape of Optic Neuropathy and Vasculopathy: the LOVE study

Submission date 26/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/04/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/04/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic retinopathy neuropathy (DRN) is the term used to describe the initial degeneration of nerve cells in the retina (the light-sensitive tissue at the back of the eye) due to elevated levels of blood sugar. However, the precise mechanism behind this condition remains unclear. This study seeks to investigate how DRN progresses by using various imaging techniques to examine the eye.

Who can participate?

Individuals aged 18 years and older with and without diabetes who live in Guangzhou, China

What does the study involve?

Comprehensive eye and general tests are performed every 2 years over a period of 4 years. Participants receive comprehensive eye and general tests and one-on-one ophthalmologist consultations based on the exam results. All the exams follow the normal clinical operation.

What are the possible benefits and risks of participating?

Participants benefit from receiving comprehensive eye and general tests and one-on-one ophthalmologist consultations based on the results. No additional risks are anticipated as 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?

December 2023 to December 2027

Who is funding the study?

Science and Technology Projects in Guangzhou (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

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

LOVE-2024-v1

Study information

Scientific Title

Landscape of optic neuropathy and vasculopathy evolution (LOVE) study

Acronym

LOVE

Study objectives

To explore the longitudinal trajectory and key metabolic markers of diabetic optic neurodegeneration based on large population cohorts and multimodal ocular imaging in vivo

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/01/2024, Zhongshan Ophthalmic Center Ethics Committee of Sun Yat-sen University (No. 7 Jinsui Road, Zhujiang New Town, Guangzhou, 510060, China; +86 (0)20 87332529; zocethics@163.com), ref: 2024KYPJ003

Study design

Retrospective and prospective ambispective cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Optic neuropathy in individuals with diabetes

Interventions

The LOVE study is a retrospective and prospective ambispective cohort study, including individuals with and without diabetes who attend Zhongshan Ophthalmic Center (ZOC) screening. All individuals in this study will be followed up every 2 years over a continuous period of 4 years. The examinations include questionnaire surveys, general physical examinations, blood sample collection, regular ocular examinations (such as intraocular pressure, refraction), (ultra-widefield) optical coherence tomography (OCT), ultra-widefield OCT angiography (OCTA), and (ultra-widefield) fundus photography.

Intervention Type

Other

Primary outcome(s)

Longitudinal change of peripapillary retinal nerve fiber layer thickness measured using optical coherence tomography (OCT) in eligible participants at baseline and each follow-up visit (2 and 4 years)

Key secondary outcome(s)

1. Longitudinal change of macular ganglion cell-inner plexiform layer (GCIPL) thickness measured using optical coherence tomography (OCT) in eligible participants at baseline and each follow-up visit (2 and 4 years)
2. Longitudinal change of macular ganglion cell complex (GCC) thickness measured using OCT in eligible participants at baseline and each follow-up visit (2 and 4 years)
3. Longitudinal change of macular microcirculation measured using optical coherence tomography angiography (OCTA) in eligible participants at baseline and each follow-up visit (2 and 4 years)
4. Longitudinal change of microcirculation in optic nerve head measured using OCTA in eligible participants at baseline and each follow-up visit (2 and 4 years)

Completion date

30/12/2027

Eligibility

Key inclusion criteria

1. Community-registered patients with diabetes
2. Individuals who live in Guangzhou for more than 6 months
3. Aged 18 years and older
4. Individuals who are capable of cooperating with ocular examinations and meeting quality

standards

5. Individuals who voluntarily participate in this study

6. Individuals who do not participate in other trials or treatments aimed at preventing or delaying the onset and progression of diabetic retinopathy (DR)

7. Absence of retinal lesions, or retinal/macular lesions not meeting the positive criteria for referable DR

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

1. Individuals who cannot cooperate with examinations

Date of first enrolment

01/01/2017

Date of final enrolment

30/12/2024

Locations

Countries of recruitment

China

Study participating centre

Zhongshan Ophthalmic Center, Sun Yat-sen University

No. 54 Xianlie Nan Road

Yuexiu District

Guangzhou

China

510060

Sponsor information

Organisation

National Sun Yat-sen University

ROR

<https://ror.org/00mjawt10>

Funder(s)

Funder type

Government

Funder Name

Science and Technology Projects in Guangzhou (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 Dr Wei Wang (wangwei@gzzoc.com). Informed consent will be obtained before the participant joins 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 is completed.

IPD sharing plan summary

Available on request