ISRCTN99411112 https://doi.org/10.1186/ISRCTN99411112

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

Submission date
26/03/2024

Recruitment status
No longer recruiting

Registration date
03/04/2024

Overall study status
Ongoing

Last Edited
04/04/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
No. 54 Xianlie Nan Road
Yuexiu District
Guangzhou
China
510060
+86 (0)20 87334687
wangwei@gzzoc.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date

30/12/2023

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1200

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

Sponsor details
Zhongshan Ophthalmic Center
No. 54. Xianlie Nan Road
Yuexiu District
Guangzhou
China
China
+86 (0)20 87330487
wangw289@mail.sysu.edu.cn

Sponsor type
University/education

Website
http://www.nsysu.edu.tw/bin/home.php?Lang=en

ROR
https://ror.org/00mjawt10

Funder(s)

Funder type
Government

Funder Name
Science and Technology Projects in Guangzhou (China)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2026

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