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Exploring the natural history of myopic maculopathy and optic neuropathy in high myopia: Zhongshan High Myopia Cohort

Submission date
09/03/2024

Recruitment status
No longer recruiting

Registration date
12/03/2024

Overall study status
Ongoing

Last Edited
29/05/2026

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Currently, pathologies including myopic maculopathy and high myopia-associated optic neuropathy are already the most frequent causes of irreversible vision loss and blindness in East Asia. However, the exact pathogenesis of these two disorders in high myopia remains elusive. Thus, it is imperative to conduct a longitudinal study to fully understand the natural history of myopic maculopathy and optic neuropathy in high myopia, determine associated risk factors and develop a precise prediction model, which will aid in improving the monitoring of high myopia and prevent vision loss.

Who can participate?
Individuals aged between 7 and 70 years old with high myopia who permanently live in Guangzhou, China. Our participants include the subjects who completed the 8-year follow-up from Zhongshan Ophthalmic Centre–Brien Holden Vision Institute (ZOC-BHVI) High Myopia Cohort Study and newly recruited subjects with high myopia.

What does the study involve?
Comprehensive eye and general tests are performed every 2 years for 8 years. Participants receive comprehensive eye and general tests and one-on-one ophthalmologist consultations based on the exam results every 2 years. 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 every 2 years. 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 2030

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
Dr Wei Wang, wangwei@gzzoc.com (China)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
ZHMC-2023-v1

Study information

Scientific Title
Zhongshan High Myopia Cohort: the natural history of myopic maculopathy and optic neuropathy in individuals with high myopia

Acronym
ZHMC

Study objectives
The project aims to explore the natural history of myopic maculopathy and optic neuropathy in highly myopic individuals, construct an intelligent automatic analysis system based on multimodal imaging and build precise prediction models.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/03/2023, 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: 2023KYPJ090

Primary study design
Observational

Study design
Retrospective and prospective ambispective cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Individuals with high myopia

Interventions
Current interventions as of 12/03/2024:

The ZHMC study is a retrospective and prospective ambispective cohort study that includes individuals who completed the 8-year follow-up from Zhongshan Ophthalmic Centre–Brien Holden Vision Institute (ZOC-BHVI) High Myopia Cohort Study and newly recruited subjects with high myopia. All individuals with high myopia in the study will be followed up every 2 years over a continuous period of 8 years. The examinations include: questionnaire surveys (e.g. basic demographic information, general medical history), general physical examinations (e.g. height, weight), and ocular examinations (strabismus and dominant eye, visual acuity, visual field, intraocular pressure, refraction, slit lamp examination, anterior segment photography, ocular biometry , (ultra-widefield) optical coherence tomography (OCT), ultra-widefield OCT angiography (OCTA), (ultra-widefield) fundus photography and autofluorescence, fundus examination, and magnetic resonance imaging (a portion of our participants by random sampling).

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Previous interventions:

The ZHMC study is a retrospective and prospective ambispective cohort study that includes individuals from Guangzhou, China. All individuals with high myopia in the study will be followed up every 2 years over a continuous period of 8 years. The examinations include: questionnaire surveys (e.g. basic demographic information, general medical history), general physical examinations (e.g. height, weight), and ocular examinations (strabismus and dominant eye, visual acuity, visual field, intraocular pressure, refraction, slit lamp examination, anterior segment photography, ocular biometry , (ultra-widefield) optical coherence tomography (OCT), ultra-widefield OCT angiography (OCTA), (ultra-widefield) fundus photography and autofluorescence, fundus examination, and magnetic resonance imaging (a portion of our participants by random sampling).

Intervention Type
Other

Primary outcome(s)
The long-term development and progression of myopic maculopathy measured using fundus photography and optic neuropathy measured using optical coherence tomography and visual field in highly myopic populations and associated risk factors at baseline and each follow-up visit (2, 4, 6, and 8 years).

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Sphere ≤ −6.00 diopter (cylinder is not included) in both eyes
2. Aged between 7 and 70 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
7 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Secondary myopia, such as a history of retinopathy of prematurity or neonatal problems, or syndromic myopia with a known genetic disease or connective tissue disorders, such as Stickler or Marfan syndrome
2. History of laser treatment for myopia correction or any intraocular surgery affecting refractive status
3. Have autoimmunity disease such as systemic lupus erythematosus, rheumatoid arthritis;
4. Have severe health problems precluding follow-up such as end-stage heart disease, kidney disease, lung disease, or terminal cancer
5. Have significant ocular media opacity preventing fundus examinations (e.g.dense corneal opacity)
6. Unable to give their own informed consent
7. Plan to move from the area within the next 8 years

Date of first enrolment
13/03/2023

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center, Sun Yat-sen University
No. 54 Xianlie Nan Road Yuexiu District, Guangzhou, China
Guangzhou
China
510060

Sponsor information

Organisation
National Sun Yat-sen University

ROR
https://ror.org/00mjawt10

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
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/05/2026	29/05/2026	Yes	No