ISRCTN13860301 https://doi.org/10.1186/ISRCTN13860301

Artificial intelligence in ophthalmology

Submission date	Recruitment status	[ ] Prospectively registered
03/11/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/11/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/11/2021	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A cataract is a clouding of the lens of the eye. Cataract surgery to replace the lens is popular, especially refractive cataract surgery, where the surgeon uses advanced multifocal intraocular lenses (IOLs) to restore vision. Both surgical skills and the IOL power calculation are important factors for surgical outcomes. Currently, optical biometers are popular instruments in ophthalmology. Many related eye parameters have an influence on the IOL power calculation. Age-related macular degeneration (AMD) is the leading cause of severe and permanent vision loss in people over age 50 years. A precise diagnosis is very important. Compared with the traditional IOL power calculation and expert diagnosis system, deep learning provides the possibility of a more accurate IOL power calculation and an efficient diagnostic method. The aim of this study is to find a more precise and efficient deep learning algorithm for IOL power calculation and AMD diagnosis.

Who can participate?
Patients undergoing cataract surgery in the Shanxi Eye Hospital Affiliated to Shanxi Medical University (Taiyuan, Shanxi, China) and patients with AMD

What does the study involve?
All patients undergo non-invasive eye tests at the start of the study and after 1 week, 1 month, and 3 months.

What are the possible benefits and risks of participating?
Participants may benefit from a basic evaluation of their eye structure. As this is an observational study, no risks are involved.

Where is the study run from?
Shanxi Eye Hospital (China)

When is the study starting and how long is it expected to run for?
November 2019 to December 2023

Who is funding the study?
1. National Natural Science Foundation of China
2. Shanxi Eye Hospital
3. Shanxi Scholarship Council of China

Who is the main contact?
Dr Xiaogang Wang
movie6521@163.com

Contact information

Type(s)
Scientific

Contact name
Dr Xiaogang Wang

Contact details
No. 100 Fudong Street
Taiyuan
China
030002
+86 (0)13834246830
movie6521@163.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
81971697

Study information

Scientific Title
Establishment of an accurate anterior and posterior segment data analysis and diagnostic system with the combination of multimodal optical coherence tomography imaging and deep learning

Study objectives
1. The intraocular lens (IOL) power of various structures could be accurately calculated using deep learning and the swept source optical coherence tomography (OCT) system
2. An intelligent age-related macular degeneration (AMD) grading diagnosis system could be established with the combination of deep learning and the spectral-domain OCT system

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 03/11/2019, Shanxi Eye Hospital Affiliated to Shanxi Medical University (No. 100 Fudong Street, Taiyuan, China; +86 (0)351 4131791; SXYYLLWYH@163.com), ref: 2019LL130

Study design
Single-center prospective cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cataract, age-related macular degeneration

Interventions
All patients undergo biometric data capture (non-contact) with the sequence of ANTERION and then with that of IOLMaster 700 in the mesopic condition without pupil dilation. The researchers collect previous retinal disease OCT images and add new available captured retinal disease images using the Optovue XR and Heiderberg OCT systems.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ANTERION, IOLMaster 700, Optovue XR and Heiderberg OCT systems

Primary outcome(s)
Automatically measured using the SS-OCT device at baseline, 1 week, 1 month, and 3 months:
1. Axial length
2. Keratometry
3. Astigmatism
4. Anterior chamber depth
5. Lens thickness values

Automatically measured using the OCT device at baseline, 1 week, 1 month, 3 months:
1. Retinal thickness
2. Macular edema
3. Choroidal neovascularization (CNV) images

Key secondary outcome(s))
1. IOL power calculated using a free Barrett online calculator at baseline, 1 week, 1 month, and 3 months

2. Visual acuity measured using a Snellen visual chart at baseline, 1 week, 1 month, and 3 months
3. Intraocular pressure measured using a non-contact tonometer at 1 week, 1 month, and 3 months

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients undergoing cataract surgery in the Shanxi Eye Hospital Affiliated to Shanxi Medical University (Taiyuan, Shanxi, China)
2. No systemic disease
3. No pathological alteration of the anterior segment (such as keratoconus, zonular dialysis, pseudoexfoliation syndrome, corneal opacity)
4. No retinal diseases impairing visual function
5. No previous anterior or posterior segment surgery
6. If patients are diagnosed with AMD disease, the captured image can be included in the AMD and deep learning study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Patients who cannot cooperate with the data capturing procedure and fail to pass the image quality check

Date of first enrolment
01/09/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre

Shanxi Eye Hospital
No. 100 Fudong Street
Taiyuan
China
030002

Sponsor information

Organisation
Shanxi Eye Hospital

ROR
https://ror.org/02wh8xm70

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

Funder Name
Shanxi Eye Hospital

Funder Name

Shanxi Scholarship Council of China

Alternative Name(s)
SSCC, SXSCC, SSCC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The related data can be acquired by contacting Dr Xiaogang Wang (movie6521@163.com). Type of data: quantitative data, imaging data. The data will be available after the related paper is published for 1 year. A written form has to be submitted to the institution investigator and evaluated by the ethics committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes