ISRCTN12941197 https://doi.org/10.1186/ISRCTN12941197

Screening and evaluation of diabetic retinopathy via a deep learning network model

Submission date 30/09/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 02/10/2024	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 02/10/2024	**Condition category** Eye Diseases	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol
Background and study aims
The study aims to screen and evaluate diabetic retinopathy through a deep-learning network model to improve the efficiency of early detection and treatment. Diabetic retinopathy is a common complication of diabetes. If not detected and treated in time, it can lead to severe visual impairment or even blindness. Traditional screening methods rely on the judgment of eye specialists and are time-consuming and expensive. The development of deep learning technology offers new possibilities for automated, fast, and accurate screening.

Who can participate?
Diabetic patients aged over 18 years old

What does the study involve?
Participants will undergo a standard eye exam, and their results will be compared with the analysis of the model to assess its accuracy and reliability. Additionally, the study will monitor the performance of the model in different disease courses, different levels of glycemic control, and different complication states to ensure its applicability in a wide range of clinical settings.

What are the possible benefits and risks of participating?
The study hopes to demonstrate the effectiveness of the deep learning network model in screening for diabetic retinopathy, optimize the screening process, reduce healthcare costs, and ultimately improve patients' quality of life and visual health. The results of the study will provide an important reference for future clinical practice and bring benefits to patients with diabetes.

The potential risks of participating in this study are generally low, but some possible risks and discomfort should be noted. First, the study requires retinal imaging, a non-invasive examination that usually does not cause direct damage to the eye. Still, some participants may experience mild discomfort or eye strain during the examination. In addition, some participants may experience temporary blurred vision or sensitivity to light when undergoing mydriasis tests, which usually resolve on their own within a few hours after the test. It is recommended to avoid driving or operating heavy machinery during this time.

In terms of data privacy, although strict measures are taken to anonymize all collected data and guarantee that it is used only for research purposes, there is still a potential risk of data breaches. The study team will protect the privacy of participants and comply with relevant laws, regulations and ethical guidelines.

Psychological risks also need to be considered. Some participants may feel anxious or concerned about the test results, especially if there are signs of diabetic retinopathy. Appropriate counseling and support will be provided to help participants understand the test results and recommend further medical tests and treatment if necessary.

Where is the study run from?
First People's Hospital of Linping District, China

When is the study starting and how long is it expected to run for?
January 2023 to June 2024

Who is funding the study?
First People's Hospital of Linping District, China

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Screening and evaluation of diabetic retinopathy via a deep learning network model: A prospective study

Study objectives
Screening and evaluation of diabetic retinopathy via a deep learning network model

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/12/2023, Medical Ethics Committee of the First People's Hospital of Linping District of Hangzhou (NO.369, Yingbin Road, Nanyuan Street, Linping District, Hangzhou, Zhejiang Province, 311100, China; +86 0571-89169090; xc89913@163.com), ref: 042

Study design
Randomized controlled trial

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Diagnostic, Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Screening and evaluation of diabetic retinopathy via a deep learning network model

Interventions
The intervention conditions in this study will involve the screening and evaluation of diabetic retinopathy in patients using a deep-learning network model. Participants, who will be diabetic individuals aged 18 and above, will undergo comprehensive eye exams, including vision tests, fundus photography, and optical coherence tomography. The image data collected from these exams will be analyzed using deep learning algorithms to assess their accuracy and effectiveness in detecting diabetic retinopathy. To ensure the scientific validity of the intervention, the model’s predictions will be compared with traditional clinical diagnosis results. Participants will also be required to follow up regularly to monitor any changes in their condition and document the

intervention’s impact. All procedures will be conducted in strict adherence to ethical standards to guarantee participant safety and data confidentiality.

The primary outcome measure of this study was to evaluate the screening and diagnostic accuracy of the deep learning network model for diabetic retinopathy. This includes the sensitivity and specificity of the model in identifying and classifying the different stages of diabetic retinopathy. In addition, the consistency between the model prediction results and the traditional clinical diagnosis results will be compared to verify the feasibility and reliability of the model in practical clinical applications. Through the analysis of a large number of patient image data, the study aims to determine the effectiveness of deep learning network models in early detection of diabetic retinopathy, thereby improving diagnostic efficiency, reducing visual impairment in patients, and ultimately improving patients' quality of life.

The secondary outcome measure of this study was to evaluate the applicability and stability of the deep learning network model in different diabetes course and complication states. This includes the ability of the model to predict the progression of retinopathy during long-term follow-up, as well as the effectiveness of screening for different patient populations, such as patients with different disease duration and blood glucose control. The study will also examine the usefulness of the model in clinical operations, such as image processing speed, ease of operation, and impact on the training needs of medical personnel. By comprehensively analyzing these secondary metrics, the research aims to optimize the application strategies of deep learning models and improve their universality and efficacy in various clinical Settings, thus providing solid data support for personalized medicine and precision medicine.

Intervention Type
Procedure/Surgery

Primary outcome measure
The effectiveness of the deep-learning network models in the early detection of diabetic retinopathy measured using the analysis of a large number of patient image data at one timepoint

Secondary outcome measures
The applicability and stability of the deep learning network model in different diabetes courses and complication states examined using data collected on the usefulness of the model in clinical operations, such as image processing speed, ease of operation, and impact on the training needs of medical personnel at one timepoint

Overall study start date
01/01/2023

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and older
2. Diagnosed diabetes, regardless of sex, race, or type of diabetes
3. Able to understand and agree to the study agreement and be willing to sign an informed consent form

4. Able to undergo an eye exam, including vision tests, fundus photography and optical coherence tomography
5. Patients should have a complete medical history, especially regarding the treatment and control of diabetes
6. Agree to regular follow-up visits during the study to monitor their condition and evaluate the screening effectiveness of the deep learning model

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
474

Total final enrolment
474

Key exclusion criteria
1. Aged under 18 years old
2. Serious eye conditions (such as glaucoma, and macular degeneration) or other eye conditions that would interfere with retinal image analysis
3. Pregnancy or planning to become pregnant during the study period due to hormonal changes that may affect retinal conditions
4. Diabetes-related complications (such as diabetic nephropathy, and neuropathy) that are severe enough to affect study participation or results
5. Patients who are unable to understand or follow the study protocol
6. Patients who are unable to follow up regularly
7. Patients who have a serious systemic disease or unstable health condition (e.g., cardiovascular disease, and cancer) that could affect the study process or outcome
8. Patients who have participated in other clinical trials in the past 6 months, or are receiving other treatments that could affect the results of this study

Date of first enrolment
01/01/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
China

Study participating centre
First People's Hospital of Linping District
NO.369, Yingbin Road, Nanyuan Street, Linping District
Hangzhou, Zhejiang Province
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Sponsor information

Organisation
First People's Hospital of Linping District

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First People's Hospital of Linping District

Results and Publications

Publication and dissemination plan
The publication and dissemination plan for this study includes publication of the results in internationally renowned medical and ophthalmic journals, as well as presentation and presentation at relevant academic conferences. In addition, we will disseminate research

findings to clinicians and patients through channels such as hospitals and diabetic patient organizations to promote the application of deep learning network models in screening for diabetic retinopathy. Research data and results will also be shared through a public database to support further scientific research and technology development.

Intention to publish date

01/11/2024

Individual participant data (IPD) sharing plan

This study plans to share individual participant data (IPD) on appropriate academic and clinical research platforms to support further scientific research and technology development. The data will be provided after anonymisation to protect the privacy of participants. The shared data will include retinal images and related clinical information for use by vetted researchers. Access to the data will be controlled through an application and review process to ensure that it is used for legitimate academic research purposes and in compliance with relevant ethical and legal regulations.

IPD sharing plan summary

Available on request