

Exploring eye health and vision in diabetic patients with different types of retinopathy

Submission date 07/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/10/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic retinopathy is the most common cause of blindness in working populations. It is a chronic condition that will gradually compromise patients' quality of life. In the early stages, patients may be asymptomatic but still need to spare time out of work visiting the health professionals. Later, they might experience difficulties dealing with daily activities in more advanced stages, even with proper treatments. Things like interacting with people, reading, or driving may not be as easy as they used to be. In the worst scenario, affected individuals can be deprived of work, causing serious economic problems for the family and the country. It is imperative to listen to these patients and adjust the healthcare system according to their needs. No study has examined the quality of life in patients with diabetic retinopathy so far, yet this is a very important element to consider when designing clinical trials or for the care of patients with this condition. The purpose of this study is to understand how diabetic retinopathy is affecting patients' lives. This study will request the patient to answer two validated questionnaires. The whole process takes approximately 15 minutes to deliver 31 questions on how an individual feels about their vision-related quality of life.

Who can participate?

Any patients with diabetic retinopathy with available widefield fundus fluorescein angiography.

What does the study involve?

Approximately 15 minutes of telephone or face-to-face consultation to deliver a validated vision-related quality of life questionnaire.

What are the possible benefits and risks of participating?

The benefits of participating include understanding the quality of life of patients with diabetic retinopathy, informing future trial designs and for a holistic approach to patient care. There will be no expected risks as this is a non-interventional observation study. People who require support may be referred to the Eye Clinic Liaison Officer.

Where is the study run from?

Moorfields Eye Hospital, UK

When is the study starting and how long is it expected to run for?
January 2024 to March 2026. This study started recruiting on 31/11/2024 and is expected to run for one year

Who is funding the study?
Boehringer Ingelheim, Germany

Who is the main contact?
Mr Dean Mcnish-Millar (study manager), d.mcnish-millar@nhs.net

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

334031

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 64141, Boehringer Ingelheim Ltd grant codes: UK/I&M ECR_2023_00003705

Study information

Scientific Title

Investigation of retinal non-perfusion and visual function in proliferative and non-proliferative retinopathy in patients with diabetes' quality of life

Acronym

INSPIRED-Q

Study objectives

It is hypothesised that the summed area of retinal non-perfusion (RNP) would have a negative linear relationship with the quality of life score, and certain locations of RNP would have a more substantial weight in influencing the results.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 11/09/2024, London - Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8141, (0)207 104 8181, (0)2071048037 ; chelsea.rec@hra.nhs.uk), ref: 24/LO/0669

Study design

Observational cross-sectional study with a single study centre

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Proliferative and non-proliferative retinopathy in patients with diabetes

Interventions

This is a questionnaire-based observational study planned to be delivered to 220 eligible participants with a diagnosis of diabetic retinopathy and recent Optos widefield fluorescein angiography scans.

At the screening stage, the study team will review patients' electronic medical records and Optos imaging scans. Those diagnosed with diabetic retinopathy and Optos widefield fluorescein angiography scans with good image quality will be eligible for this study.

The questionnaire will be discussed with the patient at the next clinic appointment or by phone if identified from the diabetes register after sending them an invitation letter. All will be provided with a patient information sheet. If interested, the researcher will consent the patient and deliver the questions. An option to answer the questions by phone is also possible if that is preferred by the patient. A trained research member will call at the designated time to deliver the questionnaire. The whole questionnaire will take approximately 15 minutes to complete.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Patients' perceived disease burden, including mobility, self-care, usual activities, pain/discomfort and anxiety/depression, will be measured using the National Eye Institute Visual Functioning Questionnaire (NEI-VFQ 25) and EuroQol Five-Dimensional Questionnaire Five Levels Vision Bolt-on (EQ-5D-5L Bolt-on) at the time around the patient's latest fluorescein angiography.

Key secondary outcome(s)

Testing different parameters' ability to reflect a patient's quality of life by comparing each parameter's receiver operating curve (ROC) to diagnose a low NEI-VFQ 25 score cross-sectionally.

Completion date

01/03/2026

Eligibility

Key inclusion criteria

Patients with diabetic retinopathy at various levels have their last available ultrawide field fluorescein angiography done.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

220

Key exclusion criteria

1. Any media opacities that could severely affect the evaluation of retinal non-perfusion on Optos fundus fluorescein angiography.
2. Any condition other than diabetic retinopathy that, from the investigator's point of view, could severely affect the vision.

Date of first enrolment

31/10/2024

Date of final enrolment

24/09/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Moorfields Eye Hospital

162 City Road

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust

ROR

<https://ror.org/03zaddr67>

Funder(s)

Funder type

Industry

Funder Name

Boehringer Ingelheim

Alternative Name(s)

Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, BI, BIPI

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Sobha Sivaprasad, sobha.sivaprasad@nhs.net.

- The type of data: fully anonymised dataset
- When the data will become available: end of study
- For how long: 5 years from the end of the study
- By what access criteria data will be shared including with whom: anonymised data will only be shared after approval from Moorfields Research Management Committee for use in an ethics-approved project.
- For what types of analyses: as approved by an ethics committee.
- By what mechanism: directly email the chief investigator with their ethics-approved project and approval will be sought from Moorfields Research Management Committee before sharing.
- Whether consent from participants was obtained: every patient will have consented to anonymised data sharing upon participating in the study.
- Comments on data anonymisation: Fully anonymised.
- Any ethical or legal restrictions: Participant-level data will be shared for future ethics approved projects after obtaining approval from the Moorfields Research Management Committee
- Any other comments: no.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication