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

Submission date	Recruitment status	[_] Prospectively registered
07/11/2024	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/01/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2025	Nutritional, Metabolic, Endocrine	[X] 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

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334031

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Home, Hospital, Internet/virtual, Medical and other records, Telephone

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2024

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 220; UK Sample Size: 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
30/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Moorfields Eye Hospital
162 City Road
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Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.moorfields.nhs.uk/

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

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

Intention to publish date
31/12/2026

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