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Diabetic retinopathy (a complication of diabetes that affects the eyes), progression of the disease and how it responds to treatment - UK Model validation

Submission date
14/01/2023

Recruitment status
No longer recruiting

Registration date
17/01/2023

Overall study status
Completed

Last Edited
24/12/2024

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with diabetes are prone to develop complications at the back of the eye causing blindness, and are therefore screened yearly or two-yearly. If serious disease develops, additional hospital appointments are necessary for monitoring/treatment. Due to increasing pressure on hospital, it would be beneficial to have a system by which patients could be prioritised in terms of risk, and appointments allocated accordingly so the high-risk patients don't come to any harm due to delays. A model has been designed in general practitioner's gathered data.
Aims: Update already developed patient risk assessment model, test it in hospital population and measure its clinical benefit.

Who can participate?
The study will use routine practice data for patients (12 years or over) with diabetic retinopathy under care of hospital eye services.

What does the study involve?
Anonymised data will be gathered anonymously at three participating NHS trusts and analysed by researchers in the University of Birmingham. The benefits to both the patients and the care provider under different scenarios will then be measured. We will then present our findings in an expert meeting including patients where it can be discussed before making a final decision on the model’s efficacy and implementation. It does not involve any interference to the patient's ongoing treatment so there is no chance of harm.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Sajjad Haider, s.haider.2@bham.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253774

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RG_22-099, IRAS 253774, CPMS 54464

Study information

Scientific Title
Diabetic Retinopathy Progression in patients under monitoring for Treatment or Vision Loss: external validation, update, and net clinical benefit of a multivariable prediction model

Acronym
DRPTVL-UK Model validation

Study objectives
Diabetes mellitus is one of the most common chronic conditions affecting nearly 4.9 million people in UK as of 2021. With the prevalence rising each year, there is an ongoing global and UK wide increase in the number of people with diabetes mellitus and consequently DR. The detection of DR has also improved through wider population screening, further increasing the demand for Hospital Eye Services. There are delays in patients being seen, causing harm especially for the higher risk patients with diabetic retinopathy. Therefore, this bottleneck urgently needs addressing. We propose to mitigate this risk by stratifying these patients and prioritise care for higher risk patients by using a statistical model we developed in primary care data.
We now need to assess the model's performance in a secondary care population to ensure it performs adequately to identify patients at high risk of treatment or vision loss. If this model performs well for predicting risk at different time points in hospital eye services / surveillance clinics data during external validation, we propose that it could be used to prioritise individuals at higher risk of vision loss and potentially inform the length of the follow up intervals after referral to hospital eye services / surveillance clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2022, South Central - Hampshire A Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 207 104 8196; hampshirea.rec@hra.nhs.uk), ref: 22/SC/0425

Study design
Mixed methods observational retrospective multicentre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
There is no direct contact with patients. Study involves only anonymised retrospective routine practice data. Therefore not applicable.

Health condition(s) or problem(s) studied
Diabetic Retinopathy

Interventions

Routine practice anonymised data analysis, a retrospective observational cohort study. Enrolment is at referral from diabetic eye screening programme into hospital with diabetic retinopathy. Once they had an outcome whichever comes first (treatment/vision failure /discharge/transfer to another provider/study period end), the data extraction stops (censoring).

Intervention Type
Other

Primary outcome measure
The first of any of these patient outcomes: date of treatment/vision loss of three lines in EDTRS chart/discharge/transfer to another provider/study period end, will be recorded in addition to the specific nature of the outcome like what treatment was given. Data is to be extracted from clinical notes/hospital electronic databases.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Patients with diabetes aged 12 years and over with referable diabetic retinopathy (patients enter the screening programme from age 12) will be identified at referral to the NHS hospital trusts from DESP between 2013 and 2016 for close monitoring and treatment.

Participant type(s)
Patient

Age group
Other

Lower age limit
12 Years

Sex
Both

Target number of participants
2400

Total final enrolment
3659

Key exclusion criteria

Patients with the specific outcome of retinopathy treatment or vision loss at referral or those referred for reasons other than retinopathy will be excluded. Patients objecting to their information being used (through a local or national opt out scheme) will also be excluded.

Date of first enrolment
28/06/2023

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre
South Tyneside & Sunderland NHS Ft Sun
Sunderlandchildrenscentre
Durham Road
Sunderland
United Kingdom
SR3 4AG

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The dataset generated during the study will be available upon request from s.haider.2@bham.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Recruitment poster	10/11/2022	16/01/2023	No	Yes
Protocol file	version 1	19/08/2022	16/01/2023	No	No
Protocol article	protocol	03/04/2023	04/04/2023	Yes	No