

Screening intervals for diabetic retinopathy

Submission date 06/04/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 12/04/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/01/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Scanlon

ORCID ID
<http://orcid.org/0000-0001-8513-710X>

Contact details
Gloucestershire Diabetic Retinopathy Research Group
Office above Oakley Ward
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA Project: 10/66/01

Study information

Scientific Title

Development of a cost-effectiveness model for optimization of the screening interval in diabetic retinopathy screening

Acronym

CODES

Study objectives

Study aims:

1. Use demographic and routinely collected clinical information from 15000 patients in 85 Gloucestershire GP practices to develop a risk score for each patient and to identify patient groups whose risk of retinopathy progression is low and whose screening interval can be safely extended
2. Model what the influence of the grading classification error is on over referrals and under referrals and how that influence changes over time, taking into account sequential grading results and hospital outcome results, comparing screening intervals that vary according to risk score against current standard practice (annual screening intervals for all patients) and other fixed-interval approaches.
3. Extend our results to multi-ethnic populations using a dataset of 2000 Asians and 5000 Caucasians from Coventry and Warwickshire and a South London dataset of 2000 people with diabetes including 700 people of African Caribbean origin. Grading results can be made available from these datasets for at least a 3 year period. The risk score and algorithm will be tested against retinopathy grades in the two datasets where follow-up data is available
4. Determine if assigning diabetic patients to differing diabetic retinopathy screening intervals using a risk estimation model is cost-effective when compared to current practice, which is annual screening of all eligible patients with diabetes
5. Estimate the economic benefits if personalised screening intervals were to be applied to the National Screening Programme in England

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A primary research study using routinely collected clinical data to model the clinical efficacy and cost-effectiveness of variable screening intervals.

Primary study design

Observational

Secondary study design

Cross-section survey

Study setting(s)

Hospital

Study type(s)

Screening

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

Diabetic Retinopathy

Interventions

The Health Technology being assessed is a variable screening interval based on risk of diabetic retinopathy (DR) assessed using two field digital photographs after pupil dilation as used in the English National Screening Programme (ENSPDR) and other available clinical data.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

A risk-based algorithm for screening interval

Secondary outcome measures

1. Years of sight saved
2. Quality-Adjusted Life Years (QALYs) gained
3. Key recommendations for further research

Overall study start date

01/05/2012

Completion date

01/05/2014

Eligibility**Key inclusion criteria**

1. Participants over the age of 12 years
2. Diagnosed with diabetes and have attended a diabetic retinopathy screening programme in one of the study areas of Gloucestershire, Coventry and Warwickshire, South London and Nottingham.
3. Have been sent the required information about transfer of risk factor data as advised by the Department of Health funded GP2DRS (General Practice to Diabetic Retinopathy Screening) Project and they would have been given the opportunity to inform their General Practice or Screening Programme that they did not want their risk factor data transferred.
4. The participants in this study are pseudoanonymised data on those people who have attended for screening and risk factor data has been transferred according to the recommended guidelines of the GP2DRS project.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Total 24,000 -15,000 in Gloucestershire, 7000 from Coventry including 2000 Asians and 2000 from South London including 700 people of Afro-Caribbean origin .

Key exclusion criteria

1. People with diabetes under 12 years
2. Those who have not attended for screening
3. Those people who have indicated that they do not want their risk factor data transferred to the screening services.

Date of first enrolment

01/05/2012

Date of final enrolment

01/05/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Gloucestershire Diabetic Retinopathy Research Group

Cheltenham

United Kingdom

GL53 7AN

Sponsor information**Organisation**

Gloucestershire Hospitals NHS Foundation Trust (UK)

Sponsor details

c/o Mr Mark Walker
Trust Headquarters
1 College Lawn
Gloucestershire
Cheltenham
England
United Kingdom
GL53 7AG

Sponsor type

Hospital/treatment centre

Website

<http://www.gloshospitals.org.uk>

ROR

<https://ror.org/04mw34986>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK) ref: 10/66/01

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2015		Yes	No