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Screening intervals for diabetic retinopathy

Submission date	Recruitment status	[X] Prospectively registered
06/04/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/04/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/01/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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