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Effectiveness of multimodal imaging for the evaluation of retinal oedema and new vessels in diabetic retinopathy

Submission date
19/06/2017

Recruitment status
No longer recruiting

Registration date
03/08/2017

Overall study status
Completed

Last Edited
19/09/2023

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One of the most common complications of diabetes is diabetic retinopathy. This disease can cause vision loss when fluid accumulates inside the eye (known as diabetic macular oedema, DMO) and when new blood vessels grow in the eye (proliferative diabetic retinopathy, PDR). There are ever increasing numbers of people with DMO and PDR: as many as 220,000 people in the UK are thought to have DMO and 212,000 believed to have PDR. Once patients are treated, long term follow up is required for the rest of the patients' life. Currently in the UK an ophthalmologist will review a patient at each appointment to determine if they still have active disease in their eyes. Given the high numbers of patients with DMO and PDR and the need for patients to be seen at short follow-up intervals for long-term follow up it is becoming difficult for the NHS to cope with demand. The aim of this study is to assess whether a patient who has been previously successfully treated for DMO/PDR could be reviewed and assessed without a face-to-face consultation with an ophthalmologist. The study investigates whether trained ophthalmic graders (healthcare professionals who have many years' experience taking images of the back of the eyes) can interpret the photographs of the back of the patients' eyes with the same accuracy that an ophthalmologist can.

Who can participate?
Patients aged 18 or older with type 1 or 2 diabetes with previously successfully treated DMO and /or PDR in one or both eyes (DMO and/or PDR may be active or inactive at the time of the study)

What does the study involve?
Each participant attends their normal clinic appointment and goes through the standard eye tests they normally do at each visit. The ophthalmologist evaluating them determines whether active/inactive DMO/PDR is present. The participants then have two more sets of photographs taken of the back of their eyes and are asked to fill in some questionnaires. There are no follow-up visits required and the extra tests should only add around 20 minutes extra to the patients' visit. Some patients are asked if they would like to take part in some discussions where they can share their views on the new care pathway. These happen at a later date.

What are the possible benefits and risks of participating?
Participating will help to determine whether other health professionals besides doctors could look after people that have been treated for the complications of diabetes in the eye once they are considered to be stable. If this is the case, this will relieve doctor's time in the NHS and doctors could then see patients with active disease and who require treatment more promptly. This may help with waiting times in the NHS. If the study shows that having other health professionals seeing patients once they are stable is not as good as having eye doctors evaluating them, then this strategy will not be used in the NHS. There are no risks associated with the study. Taking photographs of the back of the eyes has no known side effects.

Where is the study run from?
1. The Royal Hospitals (UK)
2. Gloucestershire Hospitals (UK)
3. Central Manchester University Hospitals (UK)
4. Bristol Eye Hospital (UK)
5. Bradford Teaching Hospitals - Bradford Royal Infirmary (UK)
6. Sunderland Eye Infirmary (UK)
7. Queen Margaret Hospital (UK)
8. Moorfield Eye Hospitals (UK)
9. Sheffield Teaching Hospitals (UK)
10. King's College Hospital (UK)
11. Frimley Park Hospital (UK)
12. Oxford Eye Hospital (UK)
13. James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2017 to December 2019

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Ms Lynn Murphy (public)
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2. Prof. Noemi Lois

Contact information

Type(s)
Public

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Type(s)
Scientific

Contact name
Prof Noemi Lois

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03490318

Integrated Research Application System (IRAS)
227551

Protocol serial number
HTA 15/42/08

Study information

Scientific Title
Effectiveness of Multimodal imaging for the Evaluation of Retinal oedema And new vesseLs in Diabetic retinopathy: a diagnostic accuracy study

Acronym
EMERALD

Study objectives
The new form of surveillance for people with stable diabetic macular oedema (DMO) and/or poliferative diabetic retinopathy (PDR) will be as sensitive as the current standard of care but at a lower cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2017, Office for Research Ethics Committees Northern Ireland (ORECNI) (Business Services Organisation, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, Northern Ireland; +44 (0)28 95361400), ref: 17/NI/0124

Primary study design
Observational

Study design
Prospective cross-sectional diagnostic accuracy study

Study type(s)
Other

Health condition(s) or problem(s) studied
Proliferative diabetic retinopathy (PDR) and diabetic macular oedema (DMO)

Interventions
EMERALD has a case-referent cross-sectional diagnostic study design with both sampling (selection) of patients and data collection carried out prospectively.

Multimodal retinal imaging with subsequent review of the images by trained ophthalmic graders (new pathway) will be compared with current standard of care (ophthalmologist examining patients in clinic with imaging tests used in current practice).

Patients with previously successfully treated DMO/PDR will attend the clinic, as per standard practice, and the following will be undertaken:
1. Visual acuity testing
2. OCT
3. Fundus examination
The ophthalmologist evaluating them will confirm eligibility, obtain informed consent, and determine whether active/inactive DMO/PDR is present (reference standard).

In addition the patients will then undergo wide angle fundus imaging and 7 field ETDRS fundus imaging (index test). There is no follow up for patients – a single visit is all that is required.

Intervention Type
Other

Primary outcome(s)
Sensitivity of the new pathway (ophthalmic grader pathway) in detecting active DMO/PDR is assessed by evaluating the Case Report Forms (CRFs) at baseline

Key secondary outcome(s)
1. Specificity, concordance (agreement) between the new pathway (ophthalmic grader pathway) and the standard care pathway, positive and negative likelihood ratios are assessed by evaluating the CRFs at baseline
2. Cost-effectiveness is assessed by evaluating the CRFs and the EQ-5D questionnaire at baseline
3. Acceptability is assessed by evaluating the Focus Group Discussion feedback at baseline
4. Proportion of patients requiring subsequent full clinical assessment is assessed by evaluating the CRFs at baseline

5. Proportion of patients unable to undergo imaging, with inadequate quality images or indeterminate findings, is assessed by evaluating the CRFs at baseline

Completion date
23/12/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 12/03/2019:
1. Adults (18 years of age or older)
2. Type 1 or 2 diabetes
3. Previously successfully treated DMO and/or PDR in one or both eyes and in whom, at the time of enrolment in the study
4. DMO and/or PDR may be active or inactive
4.1. Active DMO will be defined as a central subfield retinal thickness (CRT) of > 300 microns and /or presence of intraretinal/subretinal fluid on spectral domain OCT
4.2. Inactive DMO will be defined as no intraretinal/subretinal fluid
4.3. Active PDR will be defined by the presence of sub-hyaloid/vitreous haemorrhage and/or active new vessels (new vessels with lack of fibrosis on them)
4.4. Inactive PDR will be defined by the lack of preretinal/vitreous haemorrhage and lack of active new vessels

Previous participant inclusion criteria:
1. Adults (18 years of age or older)
2. Type 1 or 2 diabetes
3. Previously successfully treated DMO and/or PDR in one or both eyes and in whom, at the time of enrolment in the study
4. DMO and/or PDR may be active or inactive
4.1. Active DMO will be defined as a central subfield retinal thickness (CRT) of > 300 microns and /or presence of intraretinal/subretinal fluid on spectral domain OCT
4.2. Inactive DMO will be defined as a CRT of <300 microns and no intraretinal/subretinal fluid
4.3. Active PDR will be defined by the presence of sub-hyaloid/vitreous haemorrhage and/or active new vessels (new vessels with lack of fibrosis on them)
4.4. Inactive PDR will be defined by the lack of preretinal/vitreous haemorrhage and lack of active new vessels

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
401

Key exclusion criteria
1. Unable to provide informed consent
2. Patients do not read, speak or understand English

Date of first enrolment
01/10/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
The Royal Hospitals Belfast
United Kingdom
BT12 6BA

Study participating centre
Gloucestershire Hospitals
United Kingdom
GL1 3NN

Study participating centre
Central Manchester University Hospitals
United Kingdom
M13 9WL

Study participating centre

Bristol Eye Hospitals
United Kingdom
BS1 2LX

Study participating centre
Bradford Teaching Hospitals
United Kingdom
BD9 6RJ

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Sunderland Eye Infirmary
United Kingdom
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Study participating centre
Queen Margaret Hospital
United Kingdom
KY12 0SU

Study participating centre
Moorefield Eye Hospitals
United Kingdom
EC1V 2PD

Study participating centre
Sheffield Teaching Hospitals
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S10 23F

Study participating centre
King's College Hospital
United Kingdom
SE5 9RS

Study participating centre

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GU16 7UJ

Study participating centre
Oxford Eye Hospital
United Kingdom
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Study participating centre
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Cheriton House
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TS4 3BW

Sponsor information

Organisation
Belfast Health and Social Care Trust

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Requests for data sharing will be reviewed on a case by case basis by the CI (Prof. Noemi Lois) and TMG. Following the publication of the primary and secondary outcomes, there may be scope to conduct additional analyses on the data collected. In such instances, formal requests for data will need to be made in writing to the CI who will discuss this with the TMG. In the event of publications arising from such analyses, those responsible will need to provide the CI with a copy of any intended manuscript for approval prior to submission. Authorship will need to take the format of "[name] on behalf of the EMERALD Clinical Trial Group" or something similar, which will be agreed by the TMG.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	02/06/2021	Yes	No
Results article	cost analysis results	03/06/2021	07/06/2021	Yes	No
Results article	primary and secondary results	31/10/2020	19/09/2023	Yes	No
Protocol article	protocol	28/06/2019	02/07/2019	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version V1.0	19/06/2017	03/08/2017	No	Yes
Participant information sheet	version V2.0	20/03/2018		No	Yes
Protocol file	version v3	20/03/2018		No	No