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Community care for neovascular age-related macular degeneration

Submission date
07/09/2018

Recruitment status
No longer recruiting

Registration date
26/09/2018

Overall study status
Completed

Last Edited
29/04/2024

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Neovascular Age-Related Macular Degeneration (nAMD) is a common vision-threatening condition affecting mainly patients over the age of 65. Effective treatments exist, but require monthly visits to hospital eye clinics for tests and eye injections for a period often of several years. At some point during follow-up the disease becomes inactive in many cases and does not need more injections. The risk of a flare-up is high, however, and patients need to continue to be seen every month for a significant period of time. Hospital-based eye clinics are struggling to cope with current and expected workload for assessing and treating patients with nAMD. Transferring care of these patients to the community closer to home would ease the workload for hospital based clinics and offer a better experience of care to our patients. Previous research showed that non-medical practitioners (optometrists) can be trained to follow-up patients with nAMD when this has become inactive. More research is needed however to show with certainty that providing care for these patients in the community by trained optometrists is safe, well-received by patients and beneficial to the NHS in terms of costs. The study will seek to show that the community based care is no less safe than hospital-based care.
We will also check what is the impact of this different way of offering care on the NHS budget and how the patients and practitioners perceive this.

Who can participate?
Patients aged 55 years or older with nAMD who have reached the inactive phase of the disease

What does the study involve?
Half of the patients that want to take part will continue to have their follow-up appointments, to make sure their disease is quiet, in the hospital eye clinics as usual. The other half, chosen by chance, will have follow-up visits every month in a community optometrist practice by trained optometrists. The research team will provide the training for community optometrists.

What are the possible benefits and risks of participating?
Participants will receive care closer to home at community optometry practices. Patient safety will be ensured through training of the community optometrists and a safety check conducted by Moorfields Eye Hospital. There are no known risks to participants taking part in this study.

Where is the study run from?
The study is led by Moorfields Eye Hospital but will involve approximately 16 NHS-based eye departments and 35-40 community optometry practices across England

When is the study starting and how long is it expected to run for?
September 2018 to April 2024

Who is funding the study?
National Institute of Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Konstantinos Balaskas
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Contact information

Type(s)
Public

Contact name
Dr Moorfields Research Admin

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
254025

ClinicalTrials.gov (NCT)
NCT03893474

Protocol serial number
Nil known

Study information

Scientific Title
Quality-Assured Follow-up of quiEscent Neovascular agE-relaTed maculaR dEgeneration by non-medical practitioners: a randomised controlled trial

Acronym
FENETRE

Study objectives
Can non-medical practitioners follow-up patients with Quiescent neovascular Age-related Macular Degeneration (QnAMD) in the community in a safe and clinically and cost effective way?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/02/2019, London-Bloomsbury research ethics committee (HRA RES centre Manchester, Manchester, M1 3DZ, United Kingdom; +44 2071048127; nrescommittee.london-bloomsbury@nhs.net), ref: 18/LO/2111

Study design
Interventional prospective multi-centre randomised controlled trial with an internal pilot and process evaluation

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Neovascular age-related macular degeneration

Interventions
Participants will be randomly allocated into either the study or control arm. Randomisation will be performed by site staff using the web based randomisation tool Sealed Envelope (http://www.sealedenvelope.com), which will be custom designed to the trial requirements. This will use randomiaed permuted blocks of varying sizes with stratification by centre, treatment regimen and number of eyes eligible at baseline (unilateral or bilateral).
The study arm will have a monthly review in a community setting by non-medical healthcare practitioners (community optometrists). Classification into ‘active’, ‘inactive’ or ‘suspicious’ will be performed at each visit. ‘Active’ and ‘suspicious’ cases will be referred to secondary care for review/treatment and will discontinue study visits but remain in the study.
The control arm will have a monthly review in secondary care as per local arrangements in participating sites. For each case (eye), a classification into ‘active’ or ‘inactive’ disease will be made. ‘Active’ cases will be referred for treatment and will discontinue study visits but remain in the study.
There will be a 12 month follow-up period.
The study will involve a development phase for community optometrist training and a pilot phase with process evaluation to assess feasibility of the recruitment plan and quality assurance on the training programme. The full trial will involve an economic evaluation and process evaluation.

Intervention Type
Other

Primary outcome(s)
The proportion of patients who reactivate within 12 months of randomisation but are not identified as having re-activated (false negatives), assessed by comparison of activity assessments made by a review of clinical vignettes and ocular imaging against a reference standard provided by an expert Reading Centre. This will be assessed monthly for 12 months.

Key secondary outcome(s))
The following are assessed monthly for 12 months:
1. Diagnostic accuracy of the intervention (community optometry follow up of QnAMD) against the reference standard (rate of false negatives and false positives)
2. Rate of over-referral (i.e. Reference Standard is quiescent but classification is ‘reactivated’ or ‘suspicious’)
3. Mean change in visual acuity (measured with habitual correction and pinhole) for patients in the intervention and control groups
4. Rate of ‘suspicious’ lesion classification in community care
5. Rate of patient non-attendance and loss to follow up in secondary and primary care

The following are assessed at the baseline, after 12 months and after 18 months:
6. Use of health services and patient costs collected via an electronic case report form (eCRF) and participant completed questionnaires
7. Costs of interventions and subsequent care to the NHS modelled over the estimated lifetime
8. Modelled estimates of visual impairment and quality-adjusted life years (QALYs) based on responses to the EQ-5D-5L

Completion date
14/04/2024

Eligibility

Key inclusion criteria
1. Receiving treatment in nAMD injection clinics
2. Reached agreed definition of disease quiescence
3. Provided informed consent
4. Aged 55 years or older
5. Ability to perform study-specific procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
707

Key exclusion criteria
1. Significant media opacities (cataracts, vitreous opacities) that do not allow good quality fundus imaging
2. Diabetic retinopathy of severity worse than mild non-proliferative stage and with any degree of diabetic maculopathy
3. History of other causes of choroidal neovascularisation (myopic, angoid streaks, inflammatory, retinal dystrophies, secondary to central serous chorioretinopathy, idiopathic)

Date of first enrolment
01/06/2019

Date of final enrolment
30/01/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
United Kingdom
EC1V 2PD

Study participating centre
Manchester Royal Eye Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Leeds Teaching Hospitals NHS Foundation Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre

Bradford Teaching Hospitals NHS Foundation Trust
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

Study participating centre
York Teaching Hospitals NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Bristol University Hospitals NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Not defined

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
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Konstantinos Balaskas (konstantinos.balaskas@moorfields.nhs.uk). Data will be shared as anonymised images for the purposes of high quality research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/05/2021	18/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes