

Community care for neovascular age-related macular degeneration

Submission date 07/09/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

konstantinos.balaskas@moorfields.nhs.uk

Contact information

Type(s)

Public

Contact name

Dr Moorfields Research Admin

Contact details

Moorfields Eye Hospital NHS Foundation Trust

London

United Kingdom

EC1V 9PD

+44 (0) 207 566 2815

Moorfields.resadmin@nhs.net

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

254025

ClinicalTrials.gov number

NCT03893474

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community, Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 randomised 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 measure

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.

Secondary outcome measures

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

Overall study start date

01/09/2018

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

Age group

Adult

Sex

Both

Target number of participants

704

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

England

United Kingdom

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

Sponsor details

162 City Road

London

England

United Kingdom

EC1V 9PD

Sponsor type

Hospital/treatment centre

Website

moorfields.nhs.uk

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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

High-impact peer-reviewed publications in Ophthalmology and Health Service Research journals will be sought. Presentations in conferences, including the Royal College of Ophthalmologists national conference, the Annual conference of the College of Optometrists, the Association for Research in Vision and Ophthalmology conference, the American Academy of Ophthalmology conference, The College of Optometrists conference will be made. As part of this research project, an on-line training program will be developed with dedicated technical infrastructure and a library of clinical lectures and webinars, delivered by City University of London. This will form the basis of a sustainable training program for optometrists seeking to extend their scope of practice in the area of care for patients with AMD. The output of this program is expected to influence the healthcare market by validating care pathways for patients with AMD in the community by trained optometrists. The outcomes of this research will be communicated to NHS England and the Department of Health to inform policy on the role of primary care in the

management of patients with AMD. The Research team and management team of the sponsor organisation will actively approach and engage key parties such as the College of Optometrists, stakeholders in the community optometry market, including multiples, LOCSU, NHS England and Clinical Commissioning Groups. A detailed engagement plan will be formulated to disseminate the results of this research in order to inform policy decisions for optimising patient care. We will also engage with Eye Charities such as the Macular Society, that is already involved with the TSC for this project and Fight for Sight in order to ensure all channels of communication to the wider patient population are utilised to disseminate the results of this research and ensure they are acknowledged, selected and introduced for use in the health and care service.

Intention to publish date

31/07/2024

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