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A community-based monitoring programme for the early detection of wet age-related macular degeneration

Submission date	Recruitment status	[_] Prospectively registered
23/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/11/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2025	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Wet age-related macular degeneration (wet AMD) is the leading cause of blindness in the UK. Affecting 40,000 new individuals every year, the prevalence is estimated to reach an average of 1.23 million people by 2050. The early detection of wet AMD in the second eye using optical coherence tomography (OCT) has been shown to result in better vision and quality of life. However, currently, there is no early detection system in place for the first eye. Due to the wide availability of OCT machines in the community, in high street optometry practices and diabetic screening programmes, this study aims to measure the adherence and acceptability of participants to a community-based monitoring program for the early detection of wet age-related macular degeneration.

Who can participate?
Anyone aged 50 years old and over with a diagnosis of dry age-related macular degeneration

What does the study involve?
Attending a community optometrist for an initial eye examination very similar to a standard eye test. If the participant is eligible, they will be randomised to one of two study arms, either attending again for a repeat examination after 12 months or attending more frequently to the community optometrist every 3 months for 12 months.

What are the possible benefits and risks of participating?
The potential benefit will be the early identification of wet age-related macular degeneration and referral to the NHS for treatment.

There are no possible risks for participating in the trial.

Where is the study run from?
Community-based optometrists based around York, Grimsby, Cleethorpes, Leeds and Teesside, UK

When is the study starting and how long is it expected to run for?
March 2024 to September 2026

Who is funding the study?
This study is funded by Roche via an investigator-initiated study grant.

Who is the main contact?
Prof Richard Gale, Richard.gale@york.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331617

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60434, F. Hoffmann-La Roche Ltd Grant Code RE23_016_331617

Study information

Scientific Title
early Detection Of neovascular age-Related mAcular Degeneration in the cOmmunity

Acronym
DORADO

Study objectives
This study aims to assess the acceptability and adherence of participants who are at high risk of developing nAMD and practitioners to a community-based OCT monitoring program.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/03/2024, East of England-Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048285; cambridgecentral.rec@hra.nhs.uk), ref: 24/EE/0009

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Optician

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Specialty: Ophthalmology, Primary sub-specialty: Retina (including Diabetes); Health Category: Eye

Interventions
This is a randomised controlled trial assessing the differences between standard care and an OCT intervention program for monitoring early signs of neovascular age-related macular degeneration (nAMD).

The target population will be participants diagnosed with dry AMD exhibiting OCT biomarkers associated with a higher risk for conversion to nAMD. Potential participants will be identified when they attend their routine clinical service in the community. The study will be advertised using posters in participating opticians, eye clinics and patient support groups for example.

The trial will aim to recruit a minimum of 130 participants within 6 months, with a 12-month follow-up. To account for 30% withdrawal of consent, inconclusive imaging and missing data, the study aims to recruit a total of 169 participants. All participants will provide informed consent for their anonymised data to be used in this trial.

Within the first 3 months of the recruitment period, the study will establish the feasibility of recruitment to the trial and will determine whether it can over-recruit to the trial during the remaining period. If not, the target of 130 participants will be recruited.

An anticipated 6% of participants will be expected to convert to late-stage disease of which 3-4% will be nAMD. Participants should be managed as a part of standard care and referred as appropriate.

Individuals attending their routine optometry or DRSS appointment will be approached about this trial if they meet the inclusion/exclusion criteria. Following a discussion about the trial and having been provided with the participant information sheet (PIS), potential participants have the option of consenting to the trial on the same day or at a later appointment.

Following consent to join the trial, participants will complete the required baseline assessments and will be randomised 1:1 using the online service from SealedEnvelope.com to one of two trial arms:
Arm 1 - Standard Care (SC): Participants will be advised to self-monitor changes in their vision using a provided AMSLER grid and to attend their opticians on a routine basis.
Arm 2 - Intervention+ (OCT): Participants will follow an enhanced monitoring program, undergoing a visual acuity assessment, OCT and colour fundus photograph on a 3-monthly basis. Between the 3-monthly assessments, participants will also be advised to self-monitor changes in their vision using a provided AMSLER grid. Participants, or their nominated carer, will receive a reminder of their appointments.

At the point of recruitment, all participants, regardless of the arm they are assigned, will undergo a visual acuity assessment, OCT and colour fundus examination. These same assessments will also be completed by all participants after 12 months. Only those participants in Arm 2 will repeat these same assessments on a 3-monthly basis. QoL and wellbeing questionnaires will be offered to the participants to complete either during this recruitment visit on site, to take home and complete with a self-addressed return envelope or to complete

over the phone at a time convenient to them. Any incomplete questionnaire will be followed up with a phone call. At the 12-month follow-up, the same set of questionnaires will be completed by all participants along with an additional questionnaire assessing the acceptability of the monitoring program.

All participants will be advised to self-monitor changes in their vision using an AMSLER grid and to contact their opticians for an assessment should they notice any changes or distortions, as per standard care practice. For any participant who attends an additional visit of this nature, a note should be made in the participant CRF, including the outcome and the date any referral to a treatment centre is made.

During the course of the trial, any participant who converts to nAMD in either eye, therefore transferring to standard care via the NHS, will be asked to continue with the visits as part of the trial up to the end-of-study assessment at 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Participant acceptability is measured using the Theoretical Framework of Acceptability (TFA) questionnaire at 12 months
2. Attendance, adherence and persistence is measured using attendance data between baseline and 12 months
3. Changes in visual acuity are measured using ETDRS or Snellen scores between baseline and 12 months
4. Changes in quality-of-life and well-being are measured using the following questionnaires at baseline and 12 months: MacDQoL, NEI-VFQ-25, EQ-5D-3L, PHQ9
5. Acceptability of participating sites in conducting the monitoring programme will be measured using the Theoretical Framework of Acceptability (TFA) questionnaire at 12 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/03/2024

Completion date
19/09/2026

Eligibility

Key inclusion criteria
1. VA > 24 letters
2. Age > 50 years
3. OCT biomarkers:
3.1. Medium drusen with pigmentary abnormalities
3.2. Large drusen with or without pigmentary abnormalities
3.3. Subretinal drusenoid deposits (pseudo-reticular drusen) with or without pigmentary abnormalities

3.4. Geographic atrophy > 175µm, extrafoveal
3.5. Vitelliform lesions with visual acuity < 62 ETDRS letters (6/18)
3.6. Serous PED without neovascularisation

Participant type(s)
Patient

Age group
Mixed

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 130; UK Sample Size: 130

Key exclusion criteria
1. Non-AMD macular degeneration, e.g., myopic degeneration, inherited macular dystrophy, MACTEL
2. Diabetic macular oedema
3. Macular haemorrhage of other causes, e.g., retinal vein occlusion
4. nAMD in both eyes
5. nAMD in one eye with the fellow eye under regular monitoring in secondary care
6. Intraretinal or subretinal haemorrhage
7. Inability to consent or comply with the trial visits
8. Inability to receive pupil dilation

Date of first enrolment
06/06/2024

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Community Stadium
Kathryn Avenue
Huntington

York
United Kingdom
YO32 9AF

Study participating centre
York Specsavers
Kiosk 1, Vangarde Shopping Park, Vangarde Way
York
United Kingdom
YO32 9AE

Study participating centre
Westcliffe Health and Specsavers - Leeds - Albion Street
Specsavers
Unit 3, 80 Albion Street
Leeds
United Kingdom
LS1 6AD

Study participating centre
Specsavers (grimsby)
31 -33 Victoria Street
Grimsby
United Kingdom
DN31 1DL

Study participating centre
Specsavers Hearcare - Bassetlaw - Cleethorpes
36 St. Peters Avenue
Cleethorpes
United Kingdom
DN35 8HL

Study participating centre
Mellis Eyecare - Thornaby
Thornaby Medical Centre
Trenchard Avenue
Thornaby
Stockton-on-tees
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TS17 0EE

Sponsor information

Organisation
University of York

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Sponsor type
Hospital/treatment centre

Website
https://www.york.ac.uk

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/08/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date