ISRCTN13798759 https://doi.org/10.1186/ISRCTN13798759

Prediction of conversion to wet age-related macular degeneration (AMD)

Submission date 22/03/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/07/2021	**Overall study status** Completed	
Last Edited 30/04/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

Age-related macular degeneration (AMD) is a common condition that affects the middle part of your vision. It usually first affects people in their 50s and 60s. It doesn't cause total blindness. But it can make everyday activities like reading and recognising faces difficult. Without treatment, your vision may get worse. This can happen gradually over several years ("dry AMD"), or quickly over a few weeks or months ("wet AMD"). Patients with wet age-related macular degeneration (wAMD) in one eye are at risk of developing wAMD in the second "normal" eye (fellow eye) as well. This risk increases yearly and one of the factors among these is the presence of inactive wet AMD in the fellow eye (study eye). At present, there is not sufficient knowledge to inform patients how the presence of this inactive disease in the “normal eye" would affect the risk for conversion to wet AMD, which makes counselling patients and planning difficult.

Who can participate?

Patients aged 50 to 100 years old, with age-related macular degeneration.

What does the study involve?

This study will collect retinal images from scans and markers on these retinal image scans will be looked at. The risk of conversion in the "normal eye" to wet AMD will be calculated.

The study will be divided into 2 parts:

1. Prospective: Patients with a new diagnosis of wAMD and started on antiVEGF will consent for the prospective part of the study. Optical Coherence Tomography (OCT) and Optical Coherence Tomography Angiography (OCTA) will be used to image the study eye at a baseline visit and then at 1 and 2 years later to identify and study progress of Non-exudative Choroidal Neovascularization (neCNV) to predict increased risk of conversion of inactive wAMD to wAMD.
2. Retrospective: All patients who have started on antiVEGF treatment in one eye with wAMD in the last 12-15 months and the study eye that meet the inclusion and exclusion criteria will also be included in the study for retrospective data collection. Images from scans taken as per standard care will be collected for the study at baseline and year 1 and 2.

Patients will be in the study for 2 years.

What are the possible benefits and risks of participating?
This study will not benefit you directly. The outcome of this investigation will have no impact on the management of your condition. As we will perform analysis on retinal image scans from thousands of patients with age-related macular degeneration, the results will not be identifiable to a particular individual, hence we will not be able to provide feedback specific to you. However, by taking part in this study, you will be part of an effort to better understand wet age-related macular degeneration and the effect of its treatment, and help deliver novel tools to predict the disease onset and progression.

Where is the study run from?
Moorfields Eye Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2021 to January 2025

Who is funding the study?
Boehringer Ingelheim (UK)

Who is the main contact?
Prof. Sobha Sivaprasad, sobha.sivaprasad@nhs.net

Study website
https://www.moorfields.nhs.uk/research-and-innovation

Contact information

Type(s)
Scientific

Contact name
Prof Sobha Sivaprasad

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

290536

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47988, IRAS 290536

Study information

Scientific Title
Prevalence of subclinical Non-Exudative choroidal neovascularisation and its contribution to prediction of exudatiON in fellow eyes with unilateral exudative AMD (EYE-NEON)

Acronym
EYE NEON

Study objectives
Age related macular degeneration is a leading cause of visual loss. Early detection and intervention of advanced neovascular AMD have been shown to improve visual outcomes. Once nAMD develops in one eye there is higher risk of subsequent development of choroidal neovascularization in the second eye. In a person with unilateral wAMD (exudative AMD), the risk of the contralateral or fellow eye also converting to wAMD is 10% per year from the time the first eye develops wAMD. However, not all patients convert in first year and so by 5 years, the risk of conversion is 50%. This makes it difficult to counsel patients of their risk as they can convert at anytime in the 5 years and sometimes even later. Better prediction tools are required.

Numerous imaging related risk factors have been studied for conversion of to neovascular AMD in fellow eyes of patients with unilateral exudative AMD. There is sufficient evidence that subclinical non-exudative choroidal neovascularisation (subclinical CNV) detected by OCTA exist before the eyes convert to exudative AMD. The incidence and prevalence of subclinical CNV is unclear and whether it is the strongest predictor for conversion is also unclear. The prevalence of neCNV among patients with unilateral wAMD in the fellow eye have been variable, ranging from 6% to 27% based on OCT studies. Two-year follow-up data as assessed by OCT is sparse, but one study indicated a conversion of approximately 60% within two year. Current studies reporting data from OCT have been small and typically from single institutions. Furthermore, existing studies have not reported estimates by duration of fellow eye wAMD involvement. If neCNV is included in a risk model, we may be able to improve the time to conversion in fellow eye in the first 2 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, London - City & East Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)2071048370; cityandeast.rec@hra.nhs.uk), ref: 20/PR/0897

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Age-related macular degeneration

Interventions
This is a non-interventional cohort study and divided into a retrospective and prospective part.

The retrospective part will collect retinal images that have been taken as part of routine clinical care - these will be taken at baseline and at year 1 and 2 if available.

The prospective part will scan patients using OCT and OCTA at 3 different time points: baseline, year 1 and year 2.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Age, gender, ethnicity, smoking history, and date of anti-Vascular Endothelial Growth Factor injection of non-study eye measured using patient records at baseline
2. Visual acuity of study eye using ETDRS logs measured at baseline, month 12 and 24
3. Scans of the study eye using Optical Coherence Tomography measured at baseline, month 12 and 24
4. neCNV eyes converted to wAMD measured using Blue Auto Fluorescence and Optical Coherence Tomography Angiography measured at baseline, month 12 and 24

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
15/01/2021

Completion date
01/01/2025

Eligibility

Key inclusion criteria
Consecutive patients at each site who meet the following inclusion and exclusion criteria:
1. Adults who are >=50 years and <=100 years
2. Fellow eyes of patients with unilateral treatment naïve neovascular AMD at baseline
3. Media clarity, pupillary dilation and patient cooperation for adequate imaging
4. Ability to give informed consent

Inclusion criteria for retrospective part only in addition to above:
1. Fellow eyes of patients with unilateral neovascular AMD initiated on treatment in the past 12-15 months
2. Had OCT and OCTA for study eye at baseline

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 800; UK Sample Size: 800

Key exclusion criteria
1. Treatment initiation for unilateral neovascular AMD more than 15 months prior to recruitment.
2. Late wet AMD in the study eye
3. Co-existent ocular disease: Any other ocular condition that, in the opinion of the investigator, might affect or alter visual acuity during the course of the study
4. Any patient who has opted out of their information being used for research nationally or locally at any site
5. Patients participating in a clinical trial with an ophthalmic experimental therapy will be excluded
6. Study eye (neCNV) is not treated with anti-VEGF within 6 months for non-wAMD reason

Date of first enrolment
20/04/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

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

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Royal Liverpool University Hospital
Royal Liverpool University Hospitals NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

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

Study participating centre

Royal Sussex County Hospital
Brighton and Sussex University Hospitals NHS Trust
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Bradford Royal Infirmary
Bradford Teaching Hospitals NHS Foundation Trust
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Freeman Hospital
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust

Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Belfast City Hospital
51 Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
New Cross Hospital
Royal Wolverhampton NHS Trust
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Kent and Canterbury Hospital
East Kent Hospitals University NHS Foundation Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
St. Mary's Hosptial
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol

United Kingdom
BS1 3NU

Study participating centre
The Princess Alexandra Hospital NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
West Suffolk Hospital
West Suffolk NHS Foundation Trust
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Yeovil District Hospital
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
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United Kingdom
BA21 4AT

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

Sponsor details
162 City Road
London
England
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EC1V 2PD
+44 (0)2072533411
moorfields.resadmin@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Industry

Funder Name
Boehringer Ingelheim

Alternative Name(s)
Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, BI, BIPI

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No