# Monitoring for neovascular AMD reactivation at home

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
23/10/2017		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
25/10/2017		[X] Results		
Last Edited	Condition category	[] Individual participant data		
19/07/2024	Eye Diseases			

#### Plain English summary of protocol

Current plain English summary as of 05/08/2019:

Background and study aims

Wet age-related macular degeneration (AMD) is the commonest cause of blindness in the UK. Providing prompt access to clinics for regular surveillance and treatment has proved a major challenge for the NHS. Most patients need a series of injections followed by a period of regular check-ups in case more injections are required. Wet AMD can often flare up after a period when treatment has not been required and check-ups are usually needed for several years. Vision tests completed by patients themselves at home (home monitoring tests) to detect the need for treatment could mean that patients would not need regular hospital check-ups, allowing clinic appointments to be kept for patients likely to require treatment. Home monitoring would be more convenient and less costly for both the patient and the NHS. The main aim of this study is to find out whether three home monitoring tests can detect when wet AMD needs to be treated as well as the tests currently carried out at hospital check-ups. The home monitoring tests are a paper booklet and two vision test software applications (MultiBit test and MyVisionTrack®) that run on an iPod touch.

#### Who can participate?

Patients aged ≥ 50 years old and has at least one 'study eye' meeting the inclusion criteria.

#### What does the study involve?

Participants are asked to perform the home monitoring tests weekly at home in between their standard hospital check-ups over a period of 1 to 2 years. All equipment is provided and every other aspect of care stays the same. The home monitoring test results are not known by the patients' hospital care teams. The results are compared with the ophthalmologist's diagnosis at routine hospital check-ups, made on the basis of clinical examination and the results of hospital-based tests. The acceptability of home monitoring to both participants and their carers is assessed at three of the five hospitals by interviewing a sample of participants and carers in their homes and by telephone or Skype.

What are the possible benefits and risks of participating?

The results from this study may help to improve the care for other people diagnosed with AMD in the future. This is because home eye testing might be more convenient as patients might not

need so many regular hospital check-ups. There are no known safety issues or risks with taking part in home eye testing. The only potential disadvantage is the time taken and potential inconvenience of completing the tests. The possible disadvantages are also being investigated as part of the study.

Where is the study run from?

- 1. James Paget University Hospitals Foundation NHS Trust (UK)
- 2. University Hospital Southampton Foundation NHS Trust (UK)
- 3. Royal Liverpool & Broadgreen University Hospitals NHS Trust (UK)
- 4. Belfast Health and Social Care Trust (UK)
- 5. Moorfields Eye Hospital NHS Foundation Trust (UK)
- 6. Gloucestershire Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? October 2017 to September 2021

Who is funding the study?

National Institute of Health Research (NIHR) Health Technology Assessment Programme (HTA) (15/97/02).

Who is the main contact? Dr Ruth Hogg 028 90971654 r.e.hogg@qub.ac.uk

Prof. Barney Reeves 0117 342 3143 barney.reeves@bristol.ac.uk

Previous plain English summary:

Background and study aims

Wet age-related macular degeneration (AMD) is the commonest cause of blindness in the UK. Providing prompt access to clinics for regular surveillance and treatment has proved a major challenge for the NHS. Most patients need a series of injections followed by a period of regular check-ups in case more injections are required. Wet AMD can often flare up after a period when treatment has not been required and check-ups are usually needed for several years. Vision tests completed by patients themselves at home (home monitoring tests) to detect the need for treatment could mean that patients would not need regular hospital check-ups, allowing clinic appointments to be kept for patients likely to require treatment. Home monitoring would be more convenient and less costly for both the patient and the NHS. The main aim of this study is to find out whether three home monitoring tests can detect when wet AMD needs to be treated as well as the tests currently carried out at hospital check-ups. The home monitoring tests are a paper booklet and two vision test software applications (MultiBit test and MyVisionTrack®) that run on an iPod touch.

Who can participate?
Patients aged 50 and over with AMD

What does the study involve?

Participants are asked to perform the home monitoring tests weekly at home in between their standard hospital check-ups over a period of 1 to 2 years. All equipment is provided and every other aspect of care stays the same. The home monitoring test results are not known by the

patients' hospital care teams. The results are compared with the ophthalmologist's diagnosis at routine hospital check-ups, made on the basis of clinical examination and the results of hospital-based tests. The acceptability of home monitoring to both participants and their carers is assessed at three of the five hospitals by interviewing a sample of participants and carers in their homes and by telephone or Skype.

What are the possible benefits and risks of participating?

The results from this study may help to improve the care for other people diagnosed with AMD in the future. This is because home eye testing might be more convenient as patients might not need so many regular hospital check-ups. There are no known safety issues or risks with taking part in home eye testing. The only potential disadvantage is the time taken and potential inconvenience of completing the tests. The possible disadvantages are also being investigated as part of the study.

Where is the study run from?

- 1. James Paget University Hospitals Foundation NHS Trust (UK)
- 2. University Hospital Southampton Foundation NHS Trust (UK)
- 3. Royal Liverpool & Broadgreen University Hospitals NHS Trust (UK)
- 4. Belfast Health and Social Care Trust (UK)
- 5. Moorfields Eye Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? October 2017 to March 2021

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

Who is the main contact? Prof. Barney Reeves Barney.Reeves@bristol.ac.uk

### **Contact information**

#### Type(s)

Scientific

#### Contact name

**Prof Barney Reeves** 

#### Contact details

CTEU Bristol
Level 7 Queens Building
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 34 23143
Barney.Reeves@bristol.ac.uk

#### Type(s)

#### **Public**

#### Contact name

Dr Ruth Hogg

#### **ORCID ID**

https://orcid.org/0000-0001-9413-2669

#### Contact details

School of Medicine, Dentistry and Biomedical Sciences Queen's University Belfast 97 Lisburn Rd Belfast United Kingdom BT9 7BL 028 90971654 r.e.hogg@qub.ac.uk

#### Additional identifiers

#### Protocol serial number

HTA 15/97/02

## Study information

#### Scientific Title

Monitoring for neovascular AMD reactivation at home: the MONARCH study

#### **Acronym**

**MONARCH** 

#### Study objectives

Self-monitoring vision tests performed by patients with neovascular age-related macular degeneration (AMD) at home (called "home monitoring tests") can detect occurrence and reactivation of disease with comparable accuracy to tests currently performed by hospital eye services. An integrated qualitative study is also taking place focusing on the acceptability of home-monitoring vision tests.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/159702/#/

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Current ethics approval as of 05/08/2019:

Approved 29/01/2018, the Health and Social Care Research Ethics Committee A (Office for Research Ethics Committees Northern Ireland (ORECNI), Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, Northern Ireland, BT28 2RF; 028 95361407; RECA@hscni.net), ref: 17/NI/0235.

Previous ethics approval:
Northern Ireland REC-A - submission pending

#### Study design

Diagnostic test-accuracy study with integrated qualitative component

#### Primary study design

Observational

#### Study type(s)

Diagnostic

#### Health condition(s) or problem(s) studied

Age-related macular degeneration (AMD) and neovascular age-related macular degeneration (nAMD)

#### Interventions

Current interventions as of 05/08/2019:

This study will evaluate three self monitoring vision tests; a paper booklet and two vision test software applications (MultiBit test and MyVisionTrack®) that run on an iPod touch.

Approximately ≥400 participants will be recruited from 5 hospitals who will be asked to perform the home monitoring tests weekly at home in between their standard hospital check-ups over a period of 1 to 2 years. All participants will be asked and expected to complete all three home monitoring tests weekly for both eyes. All equipment will be provided and every other aspect of care will stay the same. The home monitoring test results will not be known by patient's hospital care teams.

The objective is to estimate the test accuracy of the three tests (index tests) to self-monitor reactivation of nAMD, compared to the reference standard of the reviewing ophthalmologist's decision at a routine hospital check-up with Optical Coherence Tomography (OCT) imaging, clinical examination and Early Treatment Diabetic Retinopathy Study (EDTRS) visual acuity. Participants will complete home monitoring tests and routine hospital follow-up for at least 12 months (from consent until the end of study). They will be seen in hospital according to the recruiting hospital's standard follow-up protocol.

The outcomes of the three tests will then be compared with one another in order to evaluate the accuracy of the index test(s). The study design is cross-sectional, and involves all patients suspected of having the condition of interest (activate AMD) undergoing the index test and the reference test. Those who test positive for the condition by the reference test can be considered to be the cases, whereas those who test negative are the controls.

The acceptability of home monitoring to both participants and their carers will also be investigated at 3 of the 5 hospitals. A sample of participants and carers will be interviewed in their homes and by telephone or Skype.

#### Previous interventions:

This study will evaluate three self monitoring vision tests; a paper booklet and two vision test software applications (MultiBit test and MyVisionTrack®) that run on an iPod touch.

Approximately ≥400 participants will be recruited from 5 hospitals who will be asked to perform the home monitoring tests weekly at home in between their standard hospital check-ups over a period of 1 to 2 years. All participants will be asked and expected to complete all three home monitoring tests weekly for both eyes (so long as they have "useful" vision in both eyes). All equipment will be provided and every other aspect of care will stay the same. The home monitoring test results will not be known by patient's hospital care teams.

The objective is to estimate the test accuracy of the three tests (index tests) to self-monitor reactivation of nAMD, compared to the reference standard of the reviewing ophthalmologist's decision at a routine hospital check-up with Optical Coherence Tomography (OCT) imaging, clinical examination and Early Treatment Diabetic Retinopathy Study (EDTRS) visual acuity. Participants will complete home monitoring tests and routine hospital follow-up for at least 12 months (from consent until the end of study). They will be seen in hospital according to the recruiting hospital's standard follow-up protocol.

The outcomes of the two tests will then be compared with one another in order to evaluate the accuracy of the index test(s). The study design is cross-sectional, and involves all patients suspected of having the condition of interest (activate AMD) undergoing the index test and the reference test. Those who test positive for the condition by the reference test can be considered to be the cases, whereas those who test negative are the controls.

The acceptability of home monitoring to both participants and their carers will also be investigated at 3 of the 5 hospitals. A sample of participants and carers will be interviewed in their homes and by telephone or Skype.

#### Intervention Type

Device

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

\_

#### Primary outcome(s)

The primary outcome is classification of a study eye at a visit as having active or inactive disease. For the reference classification, this is the reviewing ophthalmologist's decision at a monitoring visit about the activity status of the eye being monitored (definitely active, definitely inactive, ambiguous). Data will also be collected on whether an injection is ordered/given, though this may not correlate perfectly with classification by lesion activity as (a) a patient may decide to refuse further injections or a patient's health may preclude it or (b) an injection may be given when a lesion is inactive, e.g. in the context of a treat-and-extend regimen. For the index texts, alternative criteria for classification will be explored to maximise test performance. Participants will complete home monitoring tests and routine hospital follow-up for at least 12 months (from consent until the end of study).

#### Key secondary outcome(s))

Current secondary outcome measures as of 05/08/2019:

- 1. The acceptability of the tests to patients and carers and their adherence to home monitoring testing regimens, measured using interviews in their homes and by telephone or Skype
- 2. Inequalities in recruitment to the study (e.g. age, sex, social economic status and visual acuity

in the better-seeing eye at diagnosis) and their impact on the ability of participants to do the tests during follow-up and the adherence of participants to weekly testing

3. Provide pilot data for the use of home monitoring to detect conversion to nAMD in the fellow eyes of patients with unilateral disease, compared to the reference standard of detection of conversion during hospital follow-up with EDTRS visual acuity and OCT imaging.

#### Previous secondary outcome measures:

- 1. The acceptability of the tests to patients and carers and their adherence to home monitoring testing regimens, measured using interviews in their homes and by telephone or Skype
- 2. Inequalities in recruitment to the study (e.g. age, sex, social economic status and visual acuity in the better-seeing eye at diagnosis) and their impact on the ability of participants to do the tests during follow-up and the adherence of participants to weekly testing

#### Completion date

30/09/2021

# Eligibility

#### Key inclusion criteria

Current participant inclusion criteria as of 05/08/2019:

- 1. Aged ≥50 years old
- 2. At least one eye meeting ALL the inclusion criteria for a study eye
- 2.1. Eye first treated for active nAMD  $\geq$  6 months ago
- 2.2. Eye first treated for active nAMD not more than 42 months ago
- 2.3. Eye currently being monitored for nAMD disease by the NHS

#### Previous participant inclusion criteria:

1. Patients ≥50 years old diagnosed with active nAMD (≥ 6 months earlier) and currently being treated with an anti-VEGF drug or monitored (i.e. with active or inactive nAMD) by the NHS 2. Within 42 months of first treatment for nAMD

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

50 years

#### Sex

All

#### Total final enrolment

297

#### Key exclusion criteria

Current participant exclusion criteria as of 05/08/2019:

- 1. Vision in the eye being monitored limited by another eye condition
- 2. Surgery in the study eye in the previous 6 months
- 3. Refractive error in the eye being monitored >-6D
- 4. Retinal or choroidal neovascularization in the eye being monitored not due to nAMD
- 5. Inability to do one or more of the proposed tests as assessed during 'further information and training' session
- 6. Unable to understand English
- 7. Unable to comply with proposed home testing
- 8. Vision is worse than Snellen score 6/60, LogMar 1.04 or 33 letters

#### Previous participant exclusion criteria:

- 1. Vision in the eye being monitored limited by another eye condition
- 2. Surgery in the study eye in the previous 6 months
- 3. Refractive error in the eye being monitored >-6D
- 4. Retinal or choroidal neovascularization in the eye being monitored not due to nAMD
- 5. Inability to do one or more of the proposed tests as assessed during 'further information and training' session
- 6. Unable to understand English
- 7. Unable to comply with proposed home testing

#### Date of first enrolment

31/07/2018

#### Date of final enrolment

30/03/2020

#### Locations

#### Countries of recruitment

United Kingdom

England

Northern Ireland

# Study participating centre James Paget University Hospitals Foundation NHS Trust

Great Yarmouth United Kingdom NR31 6LA

SO16 6YD

Study participating centre
University Hospital Southampton Foundation NHS Trust
Southampton
United Kingdom

#### Study participating centre Royal Liverpool & Broadgreen University Hospitals NHS Trust

Liverpool United Kingdom L7 8XP

Study participating centre
Belfast Health and Social Care Trust
Belfast
United Kingdom
BT9 7AB

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

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Gloucester
United Kingdom
GL1 3NN

# Sponsor information

#### Organisation

The Queen's University Belfast

#### **ROR**

https://ror.org/00hswnk62

# 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

Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. The second file containing patient identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body.

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/03/2024	08/03/2024	Yes	No
Results article		19/07/2024	19/07/2024	Yes	No
Protocol article	protocol	01/02/2021	05/10/2020	Yes	No
Basic results			20/03/2023	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes