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Monitoring for neovascular AMD reactivation at home

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

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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

Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/monarch/

Contact information

Type(s)
Scientific

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United Kingdom

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Type(s)
Public

Contact name
Dr Ruth Hogg

ORCID ID
http://orcid.org/0000-0001-9413-2669

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Diagnostic test-accuracy study

Study setting(s)
Home

Study type(s)
Diagnostic

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
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 measure
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).

Secondary outcome measures
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

Overall study start date
01/10/2017

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 ≥ 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

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
>=400

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
England

Northern Ireland

United Kingdom

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

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

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

Sponsor details
Research Governance, Ethics and Integrity
Queen’s University Belfast
University Road
Belfast
Northern Ireland
United Kingdom
BT7 1NN

Sponsor type
University/education

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

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
The protocol will be uploaded to the HTA website: https://www.journalslibrary.nihr.ac.uk/programmes/hta/159702/#/summary-of-research

The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications and through patient organisations and newsletters to patients, where available. The trialists intend to submit a manuscript for publication in March 2021.

Intention to publish date
31/03/2023

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?
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
Results article		07/03/2024	08/03/2024	Yes	No
Results article		19/07/2024	19/07/2024	Yes	No