ISRCTN07479761 https://doi.org/10.1186/ISRCTN07479761

The effectiveness of community vs. hospital eye service follow-up for patients with neovascular age-related macular degeneration with controlled disease

Submission date
17/12/2012

Recruitment status
No longer recruiting

Registration date
18/01/2013

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The 'wet' or neovascular form of age-related macular degeneration (nAMD) is currently treated with drugs called Anti-vascular endothelial growth factor (anti-VEGF) drugs. The drug is injected into the jelly-like substance inside the eye. Injections are given monthly, if necessary, until the disease process is controlled. Anti-VEGF drugs successfully control the disease in about 9 out of 10 affected people. Clinicians continue to observe patients monthly, even when no injections are needed, because there is a very high risk of needing to restart treatment at some point in the future. One of two strategies are typically used: (a) continue to review patients monthly until active disease recurs (disease comes back) and then restart treatment or (b) give treatment even if the disease appears to be inactive but review patients less frequently. The former is very burdensome for patients and the latter leads to over treatment with its associated risks and additional expense to the National Health Service (NHS). If monitoring of the need for retreatment by community optometrists could be shown to have similar accuracy compared to monitoring of the need for retreatment by ophthalmologists in hospitals, there would be a strong drive to pass the monitoring of patients whose disease is inactive to the community setting. Similar shared-care programmes exist for other eye diseases. Community optometrists would need to be able to take good quality pictures of the affected areas of the eye and assess the need for retreatment from these pictures and the clinical examination. They would then refer patients judged to require retreatment back to the hospital. Devolving monitoring to community optometrists would free up clinic capacity in the hospital and allow ophthalmologists to concentrate on monitoring and treating patients during the active phase of wet AMD, which has to be done in the hospital. The ECHoES trial aims to test whether retreatment decisions made by community optometrists for patients with nAMD whose disease has been rendered quiescent (inactive) by anti-VEGF drugs are as good as retreatment decisions made by hospital ophthalmologists. Instead of doing a new trial involving patients, hospital ophthalmologists and community optometrists will assess specific (but anonymised) patients' histories illustrated by clinical data and pictures of the eye collected in the another trial (IVAN trial). Their Retreatment decisions will be validated against a reference standard based on data collected in the IVAN trial.

We will: 1. Estimate the proportion of optometrists' and ophthalmologists' retreatment decisions classified as 'correct' (against the reference standard); 2. Quantify agreement between retreatment decisions made by optometrists and ophthalmologists and describe disagreements; 3. Investigate the influence of vignette information on retreatment decisions; 4. Estimate the cost-effectiveness of follow-up in the community by optometrists compared to follow-up by ophthalmologists in the hospital eye service (HES).

Who can participate?
Participants will be volunteers drawn from among hospital ophthalmologists (either senior trainees or consultants) and community 'high street' optometrists.

What does the study involve?
ECHoES is a virtual trial of ophthalmologists' and optometrists' decisions about the need for anti-VEGF retreatment in patients with nAMD. It will be based on specific patients' histories consisting of pictures of the eye with accompanying clinical data. Patients' histories will be drawn from information collected in a national comparative effectiveness trial of anti-VEGF drugs (the IVAN trial), to mimic the characteristics of patients judged to be eligible for follow up in the community. Ophthalmologists and optometrists will assess the same vignettes, viewing pictures and clinical data and submitting their retreatment decisions via the internet.

What are the possible benefits and risks of participating?
There are no possible benefits or risks associated with this study

Where is the study run from?
The study will be run from Queen's University Belfast

When is the study starting and how long is it expected to run for?
The study will start in March 2013 and will run for 18 months

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/129/195

Study information

Scientific Title
The Effectiveness of Community vs. Hospital Eye Service follow-up for patients with neovascular age-related macular degeneration with quiescent disease: a virtual trial

Acronym
ECHoES

Study objectives
Wet AMD is a condition which causes severe sight loss in older people and is treated with drugs that are injected monthly into the eye. When treatment is stopped patients are monitored for relapse, with treatment restarted if needed. Relapse is unpredictable. Until now only intensive regular monthly review to detect recurrence with retreatment when necessary, results in functional outcomes similar to those observed in the pivotal trials. However, regular review in the hospital eye clinic setting , blocks clinic space, uses valuable resources, is expensive and burdensome to the patients and their carers. The proposed study will exploit an existing bank of clinical data, colour fundus and OCT images collected in the course of a large UK trial which will be used to create vignettes consisting of clinical and image information which will be used to compare the performance of participating optometrists with that of HES ophthalmologists with retinal expertise.

The question of interest to the NHS is whether community optometrists can be trained to make decisions about the need for retreatment in patients with neovascular age-related macular degeneration (nAMD) whose disease has been rendered quiescent by treatment with anti-vascular endothelial growth factor (VEGF) drugs with the same accuracy as ophthalmologists working in the hospital eye service (HES). Thus, the aim of the trial is to test the hypothesis that, compared to conventional hospital eye clinic follow-up, community follow-up by optometrists (after appropriate training) is not inferior for patients with nAMD with stable vision. This hypothesis will be tested by comparing decisions made by samples of ophthalmologists working in the HES and optometrists working in the community about the need for retreatment, following a period in which patients have not required treatment. Rather than carrying out a new (prospective) trial, optometrists and ophthalmologists participating in the trial will make decisions about vignettes composed of clinical information and colour fundus (CF) and ocular coherence tomography (OCT) images collected in the course of the IVAN trial (HTA ref: 07/36 /01). Retreatment decisions made by participants in both groups will be validated against a

reference standard based on image grading data assigned by independent graders in the IVAN trial.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/11129195
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0007/81196/PRO-11-129-195.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 1RES committee, 14/05/2013, ref: 13/EM/0199

Study design
Interventional randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
This is a virtual trial and therefore there is no patient information material

Health condition(s) or problem(s) studied
Wet age-related macular degeneration (AMD)

Interventions
The intervention of interest is retreatment decision making by community optometrists.

The comparator is retreatment decision making by hospital ophthalmologists. Ophthalmologists and optometrists will access an image repository with accompanying clinical vignettes and answer questions about the need for retreatment. The web-based programme will randomly display the vignettes to the participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Participant's judgement of the need for retreatment ('Lesion reactivation, referral to hospital' vs. 'Inactive lesion, optometry review in 4 weeks' or 'Suspicious lesion, optometry review with new images in 2 weeks') compared to the reference classification.

The primary outcome for the economic evaluation will be the cost per accurate retreatment decision.

Secondary outcome measures
Secondary outcomes are:
1. Frequency of 'critical' errors judged likely to be sight-threatening, i.e. lesions that need urgent retreatment to avoid irrecoverable loss of visual acuity.
2. Judgements about the presence or absence of lesion components, i.e.: blood, exudates and subretinal fluid (SRF) in the fundus colour images; SRF, intra-retinal fluid/cysts and pigment epithelial detachment (PED) in the Optical coherence tomography (OCT) images.
3. Participant-rated confidence in the decision about the primary outcome, on a 5-point scale.

Overall study start date
01/03/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
Hospital ophthalmologists and community optometrists will be recruited.

Ophthalmologists and Optometrists will be contacted by email. Expressions of interest will be sought. There are no specific requirements for eligibility to participate other than willingness to attend specified training sessions and completion of a test of competency following the training session. In the event of more than the desired numbers applying to take part in the study, we will allocate participation status on a first come first served basis.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
48 hospital ophthalmologists and 48 community optometrists.

Key exclusion criteria
Inability to complete training successfully including:
1. Attendance in person or via the web for training seminars and
2. Satisfactory performance on a training set of vignettes

Date of first enrolment
01/03/2013

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Institute of Clinical Science
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Sponsor information

Organisation
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Sponsor type
University/education

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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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/07/2016		Yes	No
Results article	results	01/10/2016		Yes	No
Results article	cost-effectiveness results	24/10/2016		Yes	No
HRA research summary			28/06/2023	No	No