ISRCTN82148651 https://doi.org/10.1186/ISRCTN82148651

Age-related macular degeneration (AMD) Light trial

Submission date 18/09/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2013	**Overall study status** Completed	
Last Edited 01/03/2019	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Age-related macular degeneration (AMD) is believed to affect more than 14 million people in Europe and North America and is the leading cause of visual impairment in the UK. Currently there are no treatments for early AMD or for the advanced form of the disease called geographic atrophy (GA). The other advanced form of the disease is known as wet or neovascular AMD, and may be treated by injecting a drug called Ranibizumab (Lucentis®) into the eye. The causes of AMD are not yet fully understood but it has been linked to an insufficient supply of oxygen (hypoxia) to the retina at the back of the eye. The demand of oxygen by the retina is greatest at night, so this is when hypoxia is likely to have its strongest effect. By exposing the eye to dim light at night this hypoxia is reduced. In practice this involves wearing a light mask at night that emits a dim green light. The light mask is CE marked for the treatment of diabetic retinopathy. This study aim to find out if such a mask can also be used to slow the progression of AMD. As this is the first time this approach has been used to treat people with AMD, another main aim of the study is to assess the safety of this treatment.

Who can participate?
Sixty volunteers, between 55 and 88 years of age, will be recruited from hospital AMD Clinics. They will have early AMD in one eye and wet AMD in the fellow eye. Participants will be recruited at the end of the first 3 months of Lucentis ® treatment. An additional study (called a cross sectional study) will also recruit 40 people in the same age-group who have no signs of AMD, or only early changes.

What does the study involve?
At the start of the study, each participant will attend an appointment with the study researcher who will carry out a number of eye and vision tests. Then, half of the volunteers will be allocated by chance to a 'treatment' group, and will be given a light mask to wear every night for a year, whilst the other half will be allocated to a 'control' group which will not receive a light mask. Both groups will continue to receive their Lucentis® injections as usual. At each monthly check-up at the AMD clinic, participants in both groups will be invited to attend a brief meeting with the study researcher to discuss how they are getting on with the mask (if applicable), to have the

mask replaced when necessary (every 3 months), and to answer some questions about their sleep patterns. At the end of the study (after 12 months) each participant will be invited back so we can repeat the clinical tests which were carried out at the beginning of the trial.

What are the possible benefits and risks of participating?
If it is found to be effective, this therapy could slow or stop the progression of AMD. As this is the first study of its kind, a larger study with more participants will need to be carried out in the future to confirm the results. All people who are found to be suitable and are enrolled in the study will receive a complimentary £10 gift voucher. Low-level night-time light therapy has been shown to be safe. However, because this is the first study in people with AMD, safety will be a priority in this study. One possible side effect is that the light at night may disrupt sleep. Whilst this has not been a problem reported in studies of the light mask in people with diabetic retinopathy, we will monitor sleep patterns by asking each participant questions from a sleep quality questionnaire each month. We will also look at photographs taken of the retinas at the AMD clinic each month, to ensure that there are no signs that the mask is causing any damage to the eyes.

Where is the study run from?
The study has been set up by Cardiff University (UK), and the main recruitment site will be Bristol Eye Hospital. Participants for the cross-sectional study will be recruited in Bristol and Cardiff. Additional hospital sites may join the trial.

When is the study starting and how long is it expected to run for?
Recruitment will begin in March 2014 and continue until January 2015. Data collection will take place from May 2014 to March 2016. Data analysis will take place from April 2016 to June 2016.

Who is funding the study?
The study is funded by the College of Optometrists. The mask manufacturer, Polyphotonix Medical Ltd., will provide the masks free of charge, and technical support.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Protocol vs 14

Study information

Scientific Title
Low-level night-time light therapy for age-related macular degeneration

Acronym
ALight

Study objectives
This trial investigates the hypothesis that low level light presented to the eyes at night will slow the progression of early AMD, and reduce re-treatment rate of neovascular AMD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 29/10/2013, REC reference: 13/NW /0609

Study design
Phase I/IIa proof of concept randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Age-related Macular Degeneration

Interventions
Participants randomly allocated to the intervention arm of the study will wear a lightmask each night for 12 months, which provides a dim green light to illuminate the retina through the closed eye lids.

Participants in the control arm will receive no intervention beyond usual care.

Participants in both groups will receive treatment as usual for neovascular AMD. The total duration of follow-up for intervention and control arms will be 12 months.

Participants in the associated cross-sectional study will receive no intervention, and will attend for one visit only. At this visit, the outcome measure data will be collected, and analysed alongside the baseline data from the trial.

Intervention Type
Device

Phase
Phase I/II

Primary outcome(s)
There are two co-primary outcome measures for the study - one a structural measure of disease progression based on retinal imaging, and one a measure of visual function - which act as surrogate markers for disease progression:
1. The proportion of people who show disease progression in the eye with early AMD during the 12 months of the study based on analysis of retinal images (increase in drusen volume and/or progression to advanced AMD). Increase in drusen volume will be assessed based on Optical Coherence Tomography images taken at baseline and at 12 months. Progression to advanced AMD will be assessed by evaluating medical records at 12 months.
2. The rate of retinal adaptation (time taken for photoreceptors to recover their sensitivity after being exposed to a bright adapting light). This will be measured at baseline and at 12 months, and will also be assessed in participants enrolled in the associated cross-sectional study.

Key secondary outcome(s))
1. The change in drusen volume over the 12 month follow-up period. This will be measured at baseline, and at monthly appointments throughout the 12 month follow-up period. Drusen volume will also be assessed in participants enrolled in the associated cross-sectional study.
2. The number of Lucentis ® retreatments required during the year in the fellow eye, with nAMD. A review of medical records at the end of 12 months will enable us to quantify the impact of low-level night-time light therapy on the frequency of Lucentis ® retreatment in eyes with active nAMD at baseline.
3. Changes in visual function including colour discrimination thresholds (using the Colour Assessment and Diagnosis Test, City Occupational Ltd.), visual acuity. and psychophysical 14 Hz flicker thresholds. These outcomes will be measured at baseline and at 12 months, and will also be measured in participants enrolled in the associated cross-sectional study.
4. Self-report outcome measures including health related quality-of-life (EQ-5D) and visual function (VFQ-48). This outcome will be measured at baseline and at 12 months.
5. Sleep questionnaire (Pittsburgh Sleep Quality Index, PSQI) and semi structured interviews (conducted monthly by interview) to determine intervention acceptability. This will be measured at baseline, and at monthly appointments throughout the 12 month follow-up period.

Completion date
30/06/2016

Eligibility

Key inclusion criteria
All participants will be aged between 55 and 88 years of age, may be male or female, and will have a corrected ETDRS visual acuity in the test eye of 40 letters (logMAR 0.3, Snellen 6/12) or better.

Additional inclusion criteria for participants in the trial:
1. A diagnosis of neovascular AMD in one eye only. Participants will have completed within the past month their initial 3 months of Lucentis ® loading injections, and will be entering a 'treatment as required' regime, based around a 4 weekly schedule of check-ups. Fellow eye will be classified as early AMD, characterised by the presence of soft drusen and/or focal pigmentary changes, in the absence of signs of advanced AMD e.g. retinal oedema, exudates, haemorrhage, geographic atrophy.
2. Participants will need to be willing to adhere to the allocated treatment for the duration of the trial.

Additional inclusion criteria for participants in the cross-sectional study:
Normal retinal appearance (controls) or grade 1 AMD (according to the AREDS simplified scale).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Any potential participant will be excluded if they have:

1. Ocular pathology other than macular disease, including: non-AMD related fundus changes, narrow anterior angles (≤grade 1 van Herrick), amblyopia, significant cataract (LOCS III graded, above grade 2 on any criterion), central corneal/media opacity, any posterior eye condition, glaucoma, history of prodromal symptoms of closed angle glaucoma.
2. Significant systemic disease known to affect visual function (e.g. diabetes, Parkinsons disease, Alzheimers disease).
3. History of medication known to affect visual function (e.g. chloroquine, tamoxifen).
4. An insufficient level of English language comprehension to be able to carry out the questionnaires and monthly interviews with study personnel.
5. A history of falls, or a high risk of falling.

Additional exclusion criteria for participants in the trial:
1. A diagnosis of advanced AMD in both eyes.
2. Significant systemic disease that would compromise participation in a 1 year study (e.g. motor neurone disease).
3. Cognitive impairment as determined using an abridged Mini Mental State Examination (Margrain et al. 2012)
4. Oxygen mask worn at night.

Additional exclusion criteria for participants in the cross-sectional study:
Age-related macular degeneration beyond grade 1 on the AREDS simplified scale.

Date of first enrolment

01/03/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
City University London
London
United Kingdom
EC1V 0HB

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Industry

Funder Name
College of Optometrists (UK)

Funder Name
Polyphotonix Medical Ltd (UK) - Light masks and technical support

Results and Publications

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	04/09/2018	29/01/2019	Yes	No
Protocol article	protocol	24/06/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes