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The effect of 670 nm light on visual function in ageing and age-related macular degeneration

Submission date	Recruitment status	[ ] Prospectively registered
24/05/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/07/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/07/2017	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Photoreceptors are cells found at the back of the eye which convert light to an electric signal. They demand more energy than any other tissue in the body. Unfortunately, as people grow older, the energy-producing units in the cells (mitochondria) become less efficient and produce less energy. This is associated with inflammation which contributes to age-related macular degeneration (AMD) and aging in general. AMD is the most common cause of blindness in the elderly and unfortunately there is no prevention or cure for this. A molecule in the mitochondria can absorb a particular wavelength of light (670nm – which is red) and increase energy production. Studies have also shown that inflammation associated with aging and AMD is reduced by exposure to this red light. The aim of this study is to test whether exposure to 670 nm wavelength light can improve visual function in aging and AMD.

Who can participate?
Patients with dry AMD and healthy older people

What does the study involve?
Participants hold a device emitting red light to their eyes for two minutes every day for one year and their visual function is measured before, during and 1, 3, 6 and 12 months after this treatment.

What are the possible benefits and risks of participating?
This study will show whether exposure to 670 nm light can improve visual function in aging and AMD. There are no known risks.

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 2017 to February 2019

Who is funding the study?
1. Moorfields Eye Charity (UK)
2. Fight for Sight (UK)

Who is the main contact?
Dr Chrishne Sivapathasuntharam

Contact information

Type(s)
Scientific

Contact name
Dr Chrishne Sivapathasuntharam

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REDA 15/0274

Study information

Scientific Title
A pilot study to investigate the effect of 670 nm light on visual function in ageing and age-related macular degeneration

Study objectives
Photoreceptors demand more energy than other tissue in the body. Unfortunately, as people grow older, mitochondria become less efficient and produce less energy. This is associated with inflammation which contributes to age-related macular degeneration (AMD) and aging in general. AMD is the commonest cause of blindness in the elderly and unfortunately, there is no prevention or cure for this.

A molecule in mitochondria can absorb a particular wavelength of light (670nm – which is red) and increase energy production. This has been shown in different cells, including the retina. Studies have also shown that inflammation associated with aging and AMD is reduced by exposure to this red light.

This is a pilot study to see if exposure to 670 nm wavelength of light can improve visual function in aging and AMD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Stanmore Research Ethics Committee, 24/01/2017, ref: 16/LO/2022

Study design
Pilot non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants will hold a device emitting 670 nm light to their eyes for two minutes every day for one year and have their retinal function measured before, during and 1, 3, 6 and 12 months after.

Intervention Type
Device

Primary outcome measure
Visual function determined by photoreceptor function over time, measured at 1, 3, 6 and 12 months

Secondary outcome measures
Measured at 1, 3, 6 and 12 months:
1. Metrics of photoreceptor function, assessed psychophysically and electrophysiologically
2. Visual acuity and low-luminance acuity
3. Light-adapted 30 Hz flicker peak time, measured using a RETeval device
4. Anatomical changes, evaluated using SD OCT, autofluorescence and colour photographs
5. Safety and compliance of 670 nm light exposure

Overall study start date
01/01/2017

Completion date
02/02/2019

Eligibility

Key inclusion criteria
1. Patients with dry AMD and healthy aged subjects
2. Aged 50 years and above

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Co-existent ocular disease: any ocular condition is present such that, in the opinion of the investigator, might affect the inflammatory status, visual acuity or cone function during the course of the study
2. A substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by 3 lines or more (e.g. cataract would be reducing acuity to 6/12 or worse if eye was otherwise normal) and early cataract that might be susceptible to growth under the influence of 670 nm light
3. History of major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within prior 3 months or anticipated within the next 6 months following enrolment
4. Epilepsy
5. Allergies to adhesives or any other component used

Date of first enrolment
29/03/2017

Date of final enrolment
02/02/2018

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
1st Floor Maple House (Suite B)
149 Tottenham Court Road
London
England
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Moorfields Eye Charity

Funder Name
Fight for Sight

Alternative Name(s)
Fight for Sight

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2018/2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available and will be held with the sponsor.

IPD sharing plan summary
Not expected to be made available

Study outputs

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