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Trial investigating the effect of a light-therapy sleep mask on the progression of advanced diabetic retinopathy

Submission date
26/01/2016

Recruitment status
No longer recruiting

Registration date
28/01/2016

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Diabetes is a serious long-term condition where a person is unable to control their blood sugar (glucose). People living with diabetes often have to live with long-term complications of the disease. One of these complications is diabetic retinopathy, where the cells at the back of the eye (the retina) that are sensitive to light become damaged over time. This is because the mechanisms associated with diabetes can affect the oxygen supply to the retina, causing the cells to become starved of oxygen. In order to compensate for this, new blood vessels start to grow behind the retina. These blood vessels are generally very weak and prone to leakage, causing vision to deteriorate. Many of the people who suffer from diabetic retinopathy go on to develop a condition called diabetic macular edema (DME), if left untreated. This is where there is a build-up of fluid, blocking a tiny area in the centre of the retina called the macula, which is responsible for central vision (seeing what is directly ahead). Phototherapy (light therapy) is a type of treatment used to help people suffering from diabetic retinopathy. It works by wearing an eye mask to bed which delivers a precise amount of light into the eyes through closed eyelids (light-emitting sleep mask). This prevents the light-sensitive cells of the retina from adapting to the dark, so that during the night they do not require as much oxygen to work properly, helping to slow down the formation of new, weak blood vessels. The aim of this study is to find out whether wearing a light-emitting sleep mask to bed for 6 months can help to slow down the worsening of DME.

Who can participate?
Adults suffering from DME in either eye, which has caused the macula to swell to at least 220 microns in thickness

What does the study involve?
All participants are given a light-emitting sleep mask to wear every night for eight hours. The eye mask gives off a low intensity, green light which is shone onto closed eyelids during sleep. The eye mask is worn for one month, before it is returned so that the data can be analysed, and a new mask is provided so that the eye masks are worn for a total of 6 months. Participants have eye exams at the start of the study and then after 3 and 6 months to find out if wearing the

mask has made any difference to their condition. Participants also complete a questionnaire about their experience of wearing the eye mask and have their blood sugar tested at the end of the study.

What are the possible benefits and risks of participating?
A potential benefit to participants is a significant and meaningful effect by a slowing, halting, or even reversing, of the progression of the patient's retinopathy. The risks of wearing the light mask are small. The light itself is very safe and the mask has undergone significant electrical testing. There does however, remain a small chance that patients could find the masks uncomfortable which may disturb sleep.

Where is the study run from?
Royal Vinohrady Teaching Hospital (Czech Republic)

When is the study starting and how long is it expected to run for?
January 2013 to October 2013

Who is funding the study?
1. Polyphotonix Ltd. (UK)
2. Elon Medical (Czech Republic)

Who is the main contact?
Dr Luke Barclay

Contact information

Type(s)
Public

Contact name
Dr Luke Barclay

Contact details
Polyphotonix
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZPPXV1.0

Study information

Scientific Title
Prospective open label clinical trial of a phototherapeutic eye mask for patients with diabetic retinopathy

Study objectives
Preventing retinal adaptation to darkness may alter disease progression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Vinohrady Teaching Hospital, 06/02/2013, ref: EK-VP/08/2013 1/2013

Study design
Single-centre prospective open-label non-randomised clinical trial

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 the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Diabetic retinopathy

Interventions
All participants, having been screened and consented, are given a light-emitting sleep mask to be worn each night for 6 months. The masks emit a low intensity, green light (peak wavelength 504±5nm and intensity of 74±10cd/m^2) into their eyes through their closed eyelids for a maximum of 8 hours each night during sleep. The masks last for 1 month, at the end of which time they have to be returned (for analysis) and replaced. Initial and follow-up assessments are carried out at baseline, 3 and 6 months.

Intervention Type
Device

Primary outcome measure

1. Best corrected visual acuity (VA) is assessed at a distance of 4 metres using ETDRS boards at baseline, 3 and 6 months
2. Macular thickness is assessed by spectral domain optical coherence tomography (OCT) at baseline, 3 and 6 months

Secondary outcome measures
1. Compliance with treatment is assessed by mask usage time (recorded by the masks) after 6 months of use
2. Experience of use is assessed using a questionnaire (specially designed for the purpose of this study) after 6 months of use
3. Control of diabetes is assessed by measuring glycated haemoglobin (HbA1c) at baseline and 6 months

Overall study start date
01/01/2013

Completion date
01/10/2013

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Diabetic macular edema (DME) greater than 220um (central subfield thickness) in either eye

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
Patients presenting with significant coneal opacity that precludes OCT and fundus photography.

Date of first enrolment
01/03/2013

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Czech Republic

Study participating centre
Royal Vinohrady Teaching Hospital
Šrobárova 1150/50
Prague
Czech Republic
10034

Sponsor information

Organisation
PolyPhotonix Ltd.

Sponsor details
Polyphotonix
Discovery 1, Netpark
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TS21 3FH

Sponsor type
Industry

ROR
https://ror.org/02j3x9q40

Funder(s)

Funder type
Industry

Funder Name
Polyphotonix Ltd.

Funder Name
Elon Medical

Results and Publications

Publication and dissemination plan
The investigators and sponsor intend to publish the findings of this trial in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/12/2017	18/01/2019	Yes	No