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CLEOPATRA study: the clinical efficacy and safety of light-masks at preventing dark adaptation in the treatment of non-centre-involving diabetic macular oedema

Submission date
18/02/2014

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
10/01/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
As a complication of diabetes, fluid may build up at an area of the retina of the eye called the macula. This is called diabetic macular oedema (DMO). Retinal thickening involving the centre of the macula is known as centre-involving macular oedema and is the most severe form of DMO. The natural history of the disease is to progress from non-centre-involving DMO to centre-involving DMO. There are no treatment options for non-centre-involving DMO except for management of diabetes and high blood pressure. Therefore, there is a need for both treatment and prevention of progression of non-centre-involving DMO. The light mask is a device designed to illuminate the patient's closed eyelids during sleep, preventing dark adaptation. The aim of this study is to find out whether wearing light masks during sleep at night is safe and will prevent the progression of non-centre-involving DMO.

Who can participate?
Men and women aged 18 years or over with early DMO.

What does the study involve?
Participants will be randomly allocated to either use a light mask during sleep at night or to use a dummy mask without light. The participants will be monitored over 24 months with four monthly visits to the clinic to assess the progression of DMO.

What are the possible benefits and risks of participating?
In terms of benefits to participants, the light masks may reduce the early non-centre-involving DMO and decrease the rate of progression of DMO to the centre. If the light masks are found to be effective, it would increase our understanding of DMO and provide a prevention and treatment option. The risks of wearing the masks are small, because the masks have been examined for safety. There remains a small risk that the masks might disturb sleep so we propose to test for sleep disturbance and daytime drowsiness by the use of questionnaires.

Where is the study run from?
15 NHS trusts in England (UK).

When is the study starting and how long is it expected to run for?
April 2014 to June 2018

Who is funding the study?
MRC-NIHR Efficacy and Mechanism Evaluation Programme (UK).

Who is the main contact?
Dr Sobha Sivaprasad
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
16163

Study information

Scientific Title
A multicentre phase III randomised controlled single-masked clinical trial to test the clinical efficacy and safety of LightMasks at preventing dark adaptation in the treatment of non-centre-involving diabetic macular oedema

Acronym
CLEOPATRA

Study objectives
A multicentre phase III randomised controlled single-masked clinical trial to explore whether wearing light-masks during sleep at night reduces, relative to the dummy masks, the maximal zone thickness in the study eye as measured by OCT in patients with non-centre-involving DMO at 24 months.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=16163

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Dulwich, ref.: 12/LO/0145

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Eye; Subtopic: Both, Other, Eye (all Subtopics); Disease: Retinopathy, Diabetic Control, Other, Retina (including diabetes)

Interventions
Mask, Patients will either wear a Light Mask or a dummy mask whilst they sleep at night.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
OCT; Timepoint(s): difference between arms in the change from baseline in absolute thickness at the zone of maximum thickness

Key secondary outcome(s)
1. Centre-involving macular oedema; Timepoint(s): Difference between arms in progression to centre-involving macular oedema.
2. Compliance of light masks.; Timepoint(s): Compliance rate of the light masks over 24 months
3. Macular laser treatment/anti-VEGF treatment.; Timepoint(s): Difference between the arms in the proportion requiring macular laser treatment/anti-VEGF treatment.
4. Occurrence of centre-involving macular oedema; Timepoint(s): Difference between arms in the time to occurrence of centre-involving macular oedema.
5. Progression of retinopathy as measured by ETDRS severity levels; Timepoint(s): Proportion of participants that show progression of retinopathy as measured by ETDRS severity levels.
6. Retinal thickness; Timepoint(s): Change in retinal thickness in each of the 9 ETDRS zones and macular volume.
7. Visual Acuity; Timepoint(s): Mean change in visual acuity.

Completion date

30/11/2016

Eligibility

Key inclusion criteria
1. Subjects of either sex aged 18 years or over
2. Diagnosis of diabetes mellitus (type 1 or type 2). Any one of the following will be considered to be sufficient evidence that diabetes is present:
2.1.Current regular use of insulin for the treatment of diabetes
2.2. Current regular use of oral antihyperglycaemic agents for the treatment of diabetes
2.3. Documented diabetes by ADA and/or WHO criteria
3. Best corrected visual acuity in the study eye better than 55 ETDRS letters (Snellen VA 6/18).
4. On clinical exam, retinal thickening due to early DMO not involving the central 100 µm of the macula characterised by presence of microaneurysm, exudates or oedema and OCT evidence of increased retinal thickness in at least 1 noncentral ETDRS zone of ≥320 µm.
5. Previous macular laser, intravitreal steroids or anti-VEGF treatment is permitted provided the last laser was done at least 4 months before date of recruitment.
6. Media clarity, pupillary dilation and subject cooperation sufficient for adequate fundus photographs
7. Ability to return for study visits
8. Ability to give informed consent throughout the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
The following exclusions apply to the study eye only (i.e. they may be present for the non study eye):
1. Centre-involving macular oedema defined as central subfield on OCT >300 um.
2. Macular oedema is considered to be due to a cause other than DMO.
3. An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular oedema or alter visual acuity during the course of the study (e.g. vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, IrvineGass syndrome, etc).
4. History of treatment for DMO at any time in the past 4 months (such as focal/grid macular photocoagulation, intravitreal or peribulbar corticosteroids, anti-VEGF drugs, or any other treatment) in the study eye
5. History of panretinal scatter photocoagulation in the study eye.
6. Active proliferative diabetic retinopathy in the study eye.

7. A condition that, in the opinion of the investigator, would preclude participation in the study.
8. Patients with history of insomnia or any other sleep disturbances.
9. Corneal scarring, vitreous opacities, severe asteroid hyalosis that would inhibit proper visualisation, inability to be positioned in front of the OCT device, inability to understand the requirements of the imaging, and nystagmus.

Date of first enrolment
01/04/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
London
United Kingdom
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Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Government

Funder Name
NIHR; Grant Codes: EME 11/30/02

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	01/05/2018	10/01/2019	Yes	No