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Light and diabetic eye disease

Submission date 30/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 11/12/2013	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08/H0808/198

Study information

Scientific Title
The effect of prevention of Dark Adaptation (DA) on the progress of Diabetic Macular oEdema (DME)

Acronym
DA and DME

Study objectives
By reducing the metabolic demand of retinal rods, which is maximal in dark adaptation, retinal hypoxia in diabetic eye disease will be reduced, and the progress of diabetic eye disease reversed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Kings College Hospital Research Ethics Committee (REC) in February 2009 (ref: 08 /H0808/198)

Study design
Single centre randomised single blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Patients will sleep wearing a device ('light mask') that illuminates one (closed) eyelid. The eye is chosen at random. The other eye acts as control.
Each patient will be treated for 6 months

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Ocular coherence tomography (OCT)
2. Microperimetry
3. Colour contrast sensitivity
4. Visual acuity
5. Digital fundus photography with quantitative analysis of microaneurysms

Investigations are made at baseline, 3 and 6 months

Secondary outcome measures
None

Overall study start date
01/03/2009

Completion date
01/05/2010

Eligibility

Key inclusion criteria
1. Adults age 18-65
2. No systemic disease apart from diabetes (type I or II)
3. Symmetrical DME which cannot be treated surgically, or does not require immediate intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Any other systemic disease or severe diabetic complication
2. Any other eye condition except refractive error of > 5 D
3. History of any psychological disturbance

4. Persons of no fixed abode
5. Sleep apnoea.
6. Inability to tolerate the device, or difficulty in sleeping wearing the device.

Date of first enrolment
01/03/2009

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept. Ophthalmology
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Other

Funder Name
Internal funding

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	01/12/2011		Yes	No