

# Light and diabetic eye disease

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|--|---|---|
| <b>Submission date</b><br>30/10/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/11/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>11/12/2013       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> Individual participant data  |

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/12/2011   |            | Yes            | No              |