

Light and diabetic eye disease

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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

None

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

Study participating centre
Dept. Ophthalmology
London
United Kingdom
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Sponsor information

Organisation
King's College Hospital NHS Trust (UK)

ROR
<https://ror.org/01n0k5m85>

Funder(s)

Funder type
Other

Funder Name
Internal funding

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	01/12/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes