Author’s response to reviews

Title: The clinical efficacy and safety of light-masks at preventing dark adaptation in the treatment of early diabetic macular oedema (CLEOPATRA): A Multicentre Phase III Randomised Controlled Single-Masked Clinical trial

Authors:

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Version: 2 Date: 23 April 2014

Author’s response to reviews: see over
21 March 2014

Maria Hassard
NIHR Moorfields Biomedical Research Centre
UCL Institute of Ophthalmology
162 City Road, London
EC1V 2PD

Dear Hassard

Study title: A multicentre phase III randomised controlled single masked clinical trial to test the clinical efficacy of LightMasks at preventing dark adaptation in the treatment of early diabetic macular oedema

REC reference: 13/LO/0145
Amendment number: Am03: Update to protocol & supporting documents
Amendment date: 20 February 2014
IRAS project ID: 114483

The above amendment was reviewed at the meeting of the Sub-Committee held on 11 March 2014.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation with regards to the updated protocol.

Approved documents

The documents reviewed and approved at the meeting were:

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<td>Nocturia 400 tutorial video</td>
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<tr>
<td>Covering Letter</td>
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<td>Email from Lauren Leitch-Devlin 03 March 2014</td>
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<td>Instruction for use - Light mask</td>
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<tr>
<td>Instruction for use - dummy mask</td>
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Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

13/LO/0145: Please quote this number on all correspondence

Yours sincerely

PP

Dr Michael Philpot
Chair

E-mail: nrescommittee.london-dulwich@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Maria Hassard, NIHR Moorfields Biomedical Research Centre
Dr Sobha Sivaprasad, Moorfields Eye Hospital NHS Foundation Trust
Attendance at Sub-Committee of the REC meeting on 11 March 2014

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<thead>
<tr>
<th>Name</th>
<th>Profession</th>
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<tbody>
<tr>
<td>Dr Michael Philpot</td>
<td>Consultant Psychiatrist</td>
<td>Expert</td>
</tr>
<tr>
<td>Mr John Fowler</td>
<td>Research Nurse</td>
<td>Expert</td>
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