Lightmasks that prevent dark adaptation for non-central diabetic macular oedema: the CLEOPATRA RCT

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Declared competing interests of authors: Sobha Sivaprasad has received research grants, personal fees and advisory board honoraria from Bayer AG (Leverkusen, Germany), Novartis International AG (Basel, Switzerland) and Allergan plc (Dublin, Republic of Ireland), research grants and advisory board honoraria from F. Hoffman-La Roche AG (Basel, Switzerland) and Boehringer Ingelheim GmbH (Ingelheim am Rhein, Germany) and advisory board honoraria from Heidelberg Engineering GmbH (Heidelberg, Germany). Sobha Sivaprasad is also on the National Institute for Health Research (NIHR) Health Technology Assessment Commissioning Committee. Philip Hykin reports grants, personal fees and non-financial support from Novartis International AG; grants, personal fees, non-financial support and other (including travel expenses and advisory board honoraria) from Bayer; and grants and personal fees from Allergan AG outside the submitted work. Andrew Toby Prevost is a member of the NIHR Public Health Research Funding Committee.

Published February 2019
DOI: 10.3310/eme06020

Plain English summary

The CLEOPATRA RCT
Efficacy and Mechanism Evaluation 2019; Vol. 6: No. 2
DOI: 10.3310/eme06020

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The extent to which a lack of oxygen causes vessels to leak to cause diabetic macular oedema (DMO) is unclear. Inhaling 100% oxygen has been shown to improve DMO in the short term. The rod photoreceptor is a type of cell in the retina that enables night vision and allows us to adapt to the dark but requires most of the oxygen supplied to the retina for this function. This study tested the hypothesis that if we prevent the rod photoreceptors from dark adaptation by sleeping at night using a lightmask that prevents the rod from functioning, the retina may use less oxygen at night and prevent or reverse the macular oedema. In this study, we tested whether or not wearing such a lightmask can improve early DMO.

Three hundred and eight participants with early DMO from 15 NHS hospitals were randomly allocated either to wearing the lightmask at night or to non-lightmask (control) arm to evaluate the clinical efficacy and safety of the lightmask at 24 months. The participants were assessed every 4 months, compliance stressed and also resupplied with the lightmasks. The study also evaluated the role of inhaling 100% oxygen and lightmasks on visual functions in a subgroup of 28 participants to understand the mechanisms of the effect of the lightmask.

The study showed that there was no difference between the lightmask arm and the non-lightmask arm at 24 months. Compliance with wearing the lightmask reduced with time. Oxygen inhalation also did not have any effect on visual function or the macular oedema.

The study revealed that a lack of oxygen may not contribute significantly to the onset and progression of DMO. The role of rod photoreceptors in diabetic eye disease needs to be evaluated further using other methods of rod suppression.
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This report

The research reported in this issue of the journal was funded by the EME programme as project number 11/30/02. The contractual start date was in January 2014. The final report began editorial review in April 2018 and was accepted for publication in August 2018. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The EME editors and production house have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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