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Transcorneal electrical stimulation for the treatment of retinitis pigmentosa

Submission date 17/05/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 17/05/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 21/08/2019	**Condition category** Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Retinitis pigmentosa (RP) is a progressive degenerative eye disease that affects the retina, which often leads to blindness. 1 in 4000 people in the UK is affected by RP yet there is no established therapy for treating or delaying its progression.Transcorneal electrical stimulation (TES) has gained attention as a possible treatment option for RP. Research has shown that TES improves retinal cell viability and visual function. An initial small study of TES on 24 participants with RP demonstrated that it was safe and improved vision. This study aims to confirm the safety of the new CE-approved Okustim device and to further study the benefits of TES on a larger scale.

Who can participate?
Patients aged 18 and over with retinitis pigmentosa (diagnosed by an ophthalmologist). Participants, or a carer, should have sufficient motor skills to attach the device themselves. As this study seeks to ascertain the impact of TES on RP, participants with other eye diseases (e.g. diabetic retinopathy) cannot be included in the study.

What does the study involve?
All 12 recruited participants undergo weekly TES of one eye for 30 minutes for a period of 6 months. This is followed by a further 6 months of observation without stimulation giving a total participation time of 1 year. Participants are assessed at 3, 6, 9 and 12 months after their first visit with clinical examinations, investigations and questionnaires.

What are the possible benefits and risks of participating?
TES has been shown to improve the visual fields. TES may improve the sharpness of vision. TES will be delivered by the CE-marked Okustim device. Previous studies have demonstrated TES to be a low risk treatment. Some patients may experience irritation of the eye or a dry eye, which can be treated with artificial tears. Some participants have reported a 'prickly' sensation when the stimulation is applied.

When is the study starting and how long is it expected to run for?
April 2013 to April 2015

Where is the study run from?
1. The Oxford Eye Hospital (UK)
2. London Moorfields Eye Hospital (UK)

Who is funding the study?
Biomedical Research Centre Oxford and Okuvision GmbH

Who is the main contact?
Prof. Robert Maclaren
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01847365

Secondary identifying numbers
14217

Study information

Scientific Title
Transcorneal electrical stimulation for the treatment of retinitis pigmentosa: a multicentre safety study of the Okustim® system

Acronym
TESOLAUK

Study objectives
Retinitis pigmentosa (RP) is a progressive degenerative disease of the retina, which often leads to blindness. 1 in 4000 people in the UK are affected by RP yet there is no established therapy for treating or delaying its progression. Transcorneal electrical stimulation (TES) has garnered attention as a possible therapeutic option for RP. Research has shown that TES improves retinal cell viability and visual function. An initial pilot study of TES on 24 participants with RP demonstrated that it was safe and improved vision.

This study aims to confirm the safety of the new CE-approved Okustim® device and to further characterise the benefits of TES on a larger scale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, First MREC approval date 27/11/2012, ref: 12/SW/0293

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Retinitis pigmentosa

Interventions
Recruited participants will undergo weekly TES of 1 eye delivered by the CE-marked Okustim® device for 30 minutes for a period of 6 months. This will be followed by a further 6 months of observation without stimulation giving a total participation time of 1 year. Participants will be assessed at 3, 6, 9 and 12 months after their initial baseline visit by clinical examination, investigations and questionnaires.

Intervention Type
Device

Primary outcome measure
Adverse events measured at 3, 6, 9 and 12 months after commencing the trial

Secondary outcome measures
1. Application of Device; Timepoints: Two questionnaires detailing the participant's experience and opinion of the usability of the device
2. Efficacy of Intervention; Timepoints: Best corrected visual acuity, visual field assessment, microperimetry, fundus photography, and Optical coherence tomography (OCT)

Overall study start date
01/04/2013

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Male or female participants of 18 years of age or more
2. Participants with retinitis pigmentosa (diagnosed by an ophthalmologist)
3. Adult participants who have capacity
4. Visual acuity greater or equal to 0.02
5. Participants, their caregiver or a family member should have adequate motor skills to apply electrodes
6. Participants must be able to give consent and undertake a medical evaluation to assess whether they can participate in the whole study according to the protocol
7. Participant willing to allow their GP and consultant, if appropriate, to be notified of participation in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 12

Total final enrolment
14

Key exclusion criteria

1. Diabetic retinopathy
2. Neovascularisation of any origin
3. Previous arterial or venous occlusion
4. Previous retinal detachment
5. Silicone oil tamponade
6. Dry or exudative age-related macular degeneration
7. Macular oedema
8. Any form of glaucoma
9. Any form of corneal disease, which impairs visual acuity
10. Systemic disease, which may be difficult to control or manage, and may affect normal study schedule
11. Mental Illness related to bipolar affective disorders, schizoid-affective disorders and all forms of dementia
12. Simultaneous participation in another interventional study or previous interventions, where effects may still persist
13. Female participants who are pregnant, lactating or planning pregnancy during the course of the study

Date of first enrolment
01/06/2013

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Eye Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
London Moorfields Eye Hospital
London
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EC1V 2PD

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Research Services
Clinical Trials and Research Governance
Headley Way
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
BioMedical Research Centre, Oxford (UK) Grant Codes: RWAC0

Funder Name
Okuvision GmbH (Germany)

Results and Publications

Publication and dissemination plan
Interim study results were presented at the Annual Association of Research and Vision in Ophthalmology Meeting 2014 in Orlando, USA. The final study results were presented at the Annual Association of Research and Vision in Ophthalmology Meeting 2016 in Seattle, USA. A publication is currently in the processing stage.

Intention to publish date
23/07/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/12/2017	21/08/2019	Yes	No