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# Transcorneal electrical stimulation for the treatment of retinitis pigmentosa

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|---|---|---|
| **Submission date**<br>17/05/2013 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>17/05/2013 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>21/08/2019 | **Condition category**<br>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
enquiries@eye.ox.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Siegfried Wagner

### Contact details
John Radcliffe Hospital
Dept of Clinical Neurology
Level 6
West Wing
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
-
siegfried.wagner@ndcn.ox.ac.uk

# Additional identifiers

### ClinicalTrials.gov (NCT)
NCT01847365

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)
Adverse events measured at 3, 6, 9 and 12 months after commencing the trial

## Key secondary outcome(s))
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)

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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**
United Kingdom

England

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

**Study participating centre**
**London Moorfields Eye Hospital**
London
United Kingdom
EC1V 2PD

# Sponsor information

**Organisation**
University of Oxford (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

## 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |