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Efficacy and safety of retinal rejuvenation using Ellex 2RT laser in age-related maculopathy

Submission date
20/02/2012

Recruitment status
Stopped

Registration date
20/02/2012

Overall study status
Stopped

Last Edited
07/03/2016

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Age-related macular degeneration (AMD) is a leading cause of blindness amongst the elderly population and it is important to develop a preventative treatment for this disease. The aim of this study is to find out whether the 2RT laser is effective and safe as a new preventative treatment for early AMD.

Who can participate?
Patients aged 55 or over with AMD

What does the study involve?
Participants are randomly allocated to have either a one-off laser treatment or a sham treatment. Participants are followed up every 6 months for 2 years. In each visit, participants undergo vision tests and imaging of the eye.

What are the possible benefits and risks of participating?
If proven to be effective, the laser treatment may be an easy treatment to prevent the progression of early AMD to end-stage disease. The risk is the treatment may not work or it may provide too much energy or too little energy to produce the desired effect.

Where is the study run from?
King's College Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2011 to June 2014

Who is funding the study?
J P Moulton Charitable Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
10926

Study information

Scientific Title
Efficacy and safety of retinal rejuvenation using Ellex 2RT laser in age-related maculopathy (RETILASE trial)

Acronym
RETILASE

Study objectives
Age Related Macular Degeneration (AMD) is the leading cause of visual impairment amongst the elderly. In the United Kingdom, there is an estimated 608,213 patients diagnosed with AMD. This will increase to 755,867 by the end of the next decade, accounting for 22.5% of the ageing population.

The clinical hallmark of AMD is the appearance of drusen which are localized deposits or debris lying between the basement membrane of the retinal pigment epithelium (RPE) and the Bruch's membrane. They are visible ophthalmoscopically as yellow-white deposits clustered mainly in the central macula. Although drusen alone do not account for significant loss of visual acuity in AMD, they can lead to deficits in macular function such as color contrast sensitivity and macular sensitivity. Approximately 10% of the eyes with drusen progress to the advanced forms of AMD every year. There are two main forms of advanced AMD: the geographic atrophy for which there are no treatment options and the neovascular subtype characterized by the development of choroidal neovascularization (CNV) that results in profound and rapid deterioration of vision and accounts for 80% of the blindness due to this condition. Given that AMD is the leading cause of

blindness in the elderly despite the availability of costly drugs that are used to treat the advanced form (neovascular AMD), it is essential that preventive measures are available to delay progression of the disease to these advanced forms. The disease has to be curtailed at the early stages of the disease to prevent or reduce the impact on visual function. This project aims to use a minimally invasive laser technology to clear the aging retina of debris (drusen) so that the retina is rejuvenated making it less prone to the effects of multiple stressors that stimulate the progression to advanced AMD.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=10926

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/LO/1043

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Eye; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

Interventions
The patients will be randomised to either have a one off laser treatment to the macula of one eye (2RT, nano second laser technology 400um spot size at least 25 spots) and the patients in the control arm receive only a sham laser. Patients will be followed up every 6 months for 2 years. In each visit, patients will have tests of visual function and imaging of the retina.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Visual acuity; Timepoint(s): 1 year

Key secondary outcome(s)
Not provided at time of registration

Completion date
22/06/2014

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Patients of either sex aged 55 years or over
2. Diagnosis of age-related maculopathy that meet the criteria of large drusen (=125 µ) in at least 1 eye
3. Best corrected visual acuity in the study eye between 50 to 90 ETDRS letters at baseline visit
4. Media clarity, pupillary dilation, and subject cooperation sufficient for adequate fundus photographs
5. No previous macular laser therapy to study eye
6. Written informed consent and willingness and ability to be followed up for 24 months
Target Gender: Male & Female; Upper Age Limit 90 years; Lower Age Limit 55 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Drusenoid PED, Choroidal neovascularisation and geographic atrophy in the study eye
2. Macular ischaemia (FAZ > 1000µm in diameter or moderate perifoveal capillary loss in fluorescein angiogram) or diabetic retinopathy
3. Macular oedema of any cause such as wet AMD, diabetic macular oedema, pseudophakic macular oedema or taut posterior hyaloid
4. Co-existent ocular disease that in the investigators discretion would lead to decrease visual acuity by 3 lines or more by end of 12 months
5. History of thermal lasers or treatment with intravitreal antiVEGF agents or steroids for any retinal conditions
6. Participation in an investigational trial within 30 days of randomisation that involved treatment with any drug including those that has not received regulatory approval at the time of study entry
7. Anticipated major ocular surgery (including cataract extraction) for the period of the trial
8. Amblyopia in study eye
9. Known allergy to fluorescein dye or to any component of the study drug
10. Pregnancy at baseline and the patient will be withdrawn from the study if she becomes pregnant during the course of the study

Date of first enrolment
15/12/2011

Date of final enrolment
22/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Charity

Funder Name
J P Moulton Charitable Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available