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Diffuse laser treatment for prophylaxis of the fellow eye with age-related maculopathy in patients with exudative age-related macular degeneration (AMD)

Submission date
29/09/2006

Registration date
29/09/2006

Last Edited
15/04/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0116169807

Study information

Scientific Title
Diffuse laser treatment for prophylaxis of the fellow eye with age-related maculopathy in patients with exudative age-related macular degeneration (AMD)

Study objectives
Age-related macular degeneration (AMD) is the leading cause of blindness in the developed world. The formation of abnormal blood vessels (Choroidal Neovascular Vessels = CNV) under the retina is the main cause of visual loss. It is often referred to as 'wet' AMD. Once the first eye is affected, the other eye has a high risk of developing the disease. This risk is increased (>70% in 5 years) if the fellow eye has signs of early disease in the form of yellow deposits known as drusen.
Drusen disappear in over 60% of eyes treated with focal laser treatment. However, this type of laser can cause focal damage to the eye leading to a slight increase risk of developing CNV. Nonetheless, those who do not develop this complication, have better vision.
We propose to use diffuse laser treatment to make drusen disappear, in which laser energy is transmitted to a larger area of the retina. As the laser energy is applied diffusely, it is unlikely to cause focal damage and hence it is possible that this can reduce the risk of developing CNV. Diffuse laser is has previously been used as a treatment for wet AMD, and it has been shown to be a safe procedure.

The aim of this study is to evaluate whether diffuse laser treatment reduce the rate of CNV development in the fellow eye of patients with wet AMD and hence maintain stable vision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Age-related macular degeneration (AMD)

Interventions
Age-related macular degeneration (AMD) is one of the leading causes of blindness in the western world. Currently there is no cure for this disease and treatment options for stabilising the vision are limited and expensive.
AMD can be identified in its early stages by the appearance of pigment changes and yellow deposits (drusen) which form in the macular. At this stage the patient usually has minimal symptoms. There is however a high risk of CNV formation which is the blinding condition. We would like to enrol patients at the early stage of the disease to see if our proposed treatment will reduce their risk of converting to CNV.
Eligible patients will be referred to the principle investigator for the project who will explain the aims and limitations of the study including the background data, study design and relevant risks and benefits. Written informed consent will be obtained and a patient information leaflet including contact numbers will be given to the patient. A letter explaining the details and enrolment into the trial will be sent to the GP.
Patients will be asked to attend the outpatient clinic on day 1 (baseline) with follow up at 6 monthly intervals for the first year and yearly for the second year.
The baseline visit will include documentation of visual acuity, complete ocular examination, colour fundus photography, taking a single serum sample for analysis followed by randomisation to either diffuse laser treatment or placebo treatment of the fellow eye.
The diffuse laser treatment or placebo will involve instillation of topical anaesthetic drops followed by placing a laser contact lens on the eye to be treated. A diode laser using 3000 micron spot size at 400mW (active treatment) or 0mW (placebo) is applied for 60 seconds centred on the fovea. No after care is required.
Follow up appointments will be carried out by a masked observer with repeat documentation of the visual acuity, colour fundus photography. Repeat serum sample is taken at exit from the trial. All visual symptoms are documented and a complete dilated ocular examination will be performed.
The rate of conversion to CNV will be documented and confirmed using fundus fluoresceine angiogram.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of development of CNV

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2005

Completion date
01/01/2009

Eligibility

Key inclusion criteria
Outpatients aged 55 or over with a diagnosis of exudative age-related macular degeneration in one eye and early changes of AMD (drusen and retinal pigment changes) in the other eye

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Patients in whom colour fundus photography is not possible due to ocular media opacities or other disabilities
2. Those with other retinal diseases.

Date of first enrolment
01/07/2005

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Denmark Hill
London
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SE5 9RS

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
Kings College Hospital NHS Trust R&D Consortium

Funder Name
Own Account

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration