

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 29/09/2006	Overall study status Completed	☐ Protocol
Last Edited 15/04/2016	Condition category Eye Diseases	☐ 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

Protocol serial number
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 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

Rate of development of CNV

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Denmark Hill

London

United Kingdom

SE5 9RS

Sponsor information**Organisation**

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration