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A randomized prospective study investigating the optimum power settings for selective laser trabeculoplasty (SLT) in ocular hypertension (OHT) and primary open angle glaucoma (POAG)

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
07/12/2010

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0013184505

Study information

Scientific Title

Study objectives
At the present time, although SLT is accepted as a viable treatment for OHT / POAG, there has not been a thorough assessment of the optimum Laser power settings which enable safe and effective treatment. This study aims to scientifically compare high power settings with low power settings, investigating the efficacy of treatment in lowering intraocular pressure during the follow-up period after treatment, and the incidence of adverse events related to Laser treatment. Secondary Research Objectives: None

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Ocular hypertension (OHT)

Interventions
Research participants are to be recruited from the NHS glaucoma clinic at St. Thomas' Hospital over a 6 months period, starting 1st May 2004. Eligible participants will be patients with OHT or POAG, which is uncontrolled in one or both eyes despite maximal topical medical therapy. We aim to recruit 60 patients.

Each patient will be randomized to treatment with the Laserex Solo SLT Glaucoma Laser in one of three treatment groups:
Group 1 will receive high-energy SLT (1.2mJ shots) in one or both eyes
Group 2 will receive medium energy SLT (0.8mJ shots) in one or both eyes
Group 3 will receive low-energy SLT (0.4mJ shots) in one or both eyes.

The decision to treat either one or both eyes will depend on whether the intraocular pressure is too high in one or both eyes. Therefore only eyes with uncontrolled pressure will be treated. Some patients may have both eyes treated. In these cases data for the study will only be collected for one eye. Thus, in total, 20 patients will be allocated to each of the 3 groups with 20 eyes per group (one per patient).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Visual field defect progression
2. Disc cup appearances

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2005

Completion date
01/08/2006

Eligibility

Key inclusion criteria
Patients with OHT or POAG, which is uncontrolled despite maximal topical medical therapy.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Patients who do not meet inclusion criteria

Date of first enrolment
01/08/2005

Date of final enrolment

01/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lambeth Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010		Yes	No