

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/12/2010	Condition category Eye Diseases	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

1. Visual field defect progression
2. Disc cup appearances

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Lambeth Road

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

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

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

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