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Selective Laser Trabeculoplasty and its effect on fluid flow out of the eyes

Submission date 23/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2008	**Overall study status** Completed	
Last Edited 05/04/2012	**Condition category** Eye Diseases	

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
PROTOCOL 1

Study information

Scientific Title
A randomised study of different levels of total energy delivered in Selective Laser Trabeculoplasty

Acronym
SLTLIM

Study objectives
Different levels of total energy delivered in selective laser trabeculoplasty (SLT) will have different effects on outflow facility and intra-ocular pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the St Thomas' Hospital Local Ethics Committee in September 2005 (ref: 05/Q0702/42).

Study design
Randomised prospective non-controlled two armed trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ocular hypertension (OHT) and primary open-angle glaucoma (POAG)

Interventions
Participants will be randomised to one of two different levels of total energy:
1. Treated with a lower total energy to the drainage angle
2. Treated with a higher energy level (of approximately double of the total energy as the first group)

There will only be one treatment given to each patient. Follow-up will be for three months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Intra-ocular pressure: measured with a Goldmann's applanation tonometer, using a topical anaesthetic, and fluorescein as the disclosing agent. The right eye will be measured first, followed by measurement of the left. This sequence will be repeated three times. The three measurements for each eye will be averaged and reported as intra-ocular pressure.
2. Outflow facility: measured from the rate of decay of intra-ocular pressure in the supine position during application of a recording Schiötz or pneumotonometer over a period of 4 minutes. The "R" values of the curve at every 30-second time point will be manually entered into the McLaren tonography computer program. The program fits a second-degree polynomial by least squares to the nine data points and determines the best-fit values for time 0 and time 4 minutes by extrapolation. These initial and final values of the tonometer scale reading will be used to look up the value for the facility of outflow using the 1955 scale approved by the Committee on Standardisation of Tonometers.

Outcomes will be measured at baseline, one month and three months.

Secondary outcome measures
Complications, measured at baseline, one month and three months.

Overall study start date
01/11/2006

Completion date
01/06/2008

Eligibility

Key inclusion criteria
1. Participants aged 21 - 85 years, male and female
2. Newly diagnosed ocular hypertension and primary open-angle glaucoma that require treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46

Key exclusion criteria

1. Previous intraocular surgery
2. Advanced glaucoma
3. Very high presenting intra-ocular pressure (greater than 35 mmHg)

Date of first enrolment
01/11/2006

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Ophthalmology
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guys and St Thomas NHS Foundation Trust (UK)

Sponsor details
c/o Jackie Pullen
Clinical Quality Manager
The Joint Clinical Trials Office
3rd Floor Conybeare House
Guy's Hospital
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website

http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Eye Hope (UK)

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