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

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