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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Complications, measured at baseline, one month and three months.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Guys and St Thomas NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Eye Hope (UK)

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