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# Laser-1st vs Drops-1st for Glaucoma and Ocular Hypertension

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 19/07/2012 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [X] Statistical analysis plan |
| 23/07/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 20/09/2022 | Eye Diseases | |

## Plain English summary of protocol

Background and study aims
Glaucoma is an eye disease that affects the nerve responsible for sight. This damage has no symptoms in its early stages, but when becomes severe, may even lead to loss of vision. The damage is not reversible, so the aim of treatment is to slow down the rate of damage. Ocular hypertension is a condition in which a high pressure in the eye-ball causes glaucoma in some people. Reducing the eye pressure can prevent damage to the eyesight (in some people but not all). At the moment, nearly all patients who have glaucoma or ocular hypertension are given treatment with eye-drops to lower the pressure in the eye. Once started, these are usually continued life-long. However, not all patients like to take drops. An alternative treatment involves gentle laser therapy to the front of the eye (Selective Laser Trabeculoplasty or SLT). The aim of the study is to find out whether initial treatment with SLT in patients with newly found glaucoma or ocular hypertension is better than the current standard initial treatment with topical medication alone.

Who can participate?
This trial accepts participants who have been found to have glaucoma or ocular hypertension with a decision to treat made by a consultant glaucoma specialist. The patients must be aged over 18 years and be able to provide informed consent.

What does the study involve?
Patients are randomly allocated to one of two groups. One group receives SLT first followed by usual medical therapy as required (Laser-1st) and the other group receives medical therapy without laser (Medicine-1st). The two treatments are compared, while also checking the cost-effectiveness of Laser-1st versus Medicine-1st.

What are the possible benefits and risks for participating?
There will be no immediate direct benefit to those taking part. Participants will be followed and treated in the same way as if they were not in the study, except that half of the people will be given laser as their first treatment (up to two times), before being offered eye-drops. The information we get from this study may help us to treat future patients with glaucoma better. The drop treatments planned for the study are exactly the same as those that are in normal common use by eye doctors throughout this country. Drops can have mild side effects (such as

mild discomfort or redness of the eye, that usually settles with time) or more severe ones such as making asthma (disease of the airways) worse. The laser treatment that we plan to use for half the people in this study has been used in many hundreds of thousands of people over the last 10 years. In a small number of people it can cause mild discomfort for a few days and if this is the case then mild dose of eye drops are used three times a day for three days. Very rarely the laser can make the eye pressure go up instead of down and if that happens it is necessary to take eye-drops to lower the pressure. Even more rarely (reported in only 4 people out of many hundreds of thousands) the laser has caused enough side effects to make the eye blurred for several weeks.

When is the study starting and long is it expected to run for?
October 2012 to October 2017.

Where is the study run from?
Moorfields Eye Hospital, London, UK.

Who is funding the study?
The National Institute of Health Research (NIHR), UK.

Who is the main contact?
Dr Amanda Davis
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
NCT03395535

### Secondary identifying numbers
HTA 09/104/40; Version 1.0, 23rd March 2012, GAZG1001

# Study information

### Scientific Title
Health-Related Quality of Life in two treatment pathways for newly diagnosed open angle glaucoma (OAG) and ocular hypertension (OHT): an unmasked, multi-centre, randomised controlled trial of initial selective laser trabeculoplasty (SLT) versus conventional medical therapy.

### Acronym
LiGHT

### Study objectives
Patients with ocular hypertension (OHT) or open angle glaucoma (OAG) lowering IOP with selective laser trabeculoplasty (SLT) as the primary treatment (Laser-1st) leads to a better health-related quality of life than for those started on IOP-lowering drops as their primary treatment (Medicine-1st) and that this is associated with: reduced costs and improved tolerability of treatment.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee London - City Road & Hampstead, 20/06/2012 ref: 12/LO/0940

### Study design
Unmasked multi-centre pragmatic randomised controlled 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
Glaucoma

### Interventions

Selective laser trabeculoplasty versus conventional medical therapy.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
To determine whether, in a pragmatic study that mirrors the realities of clinical decision-making, Laser-1st delivers a better HRQL at 3 years than does Medicine-1st in the management of patients with OAG and OHT.

### Secondary outcome measures
To determine whether a Laser-1st treatment pathway:
1. Costs less than the conventional treatment pathway of Medicine-1st
2. Achieves the desired level of IOP with less intensive treatment over the course of the study
3. Leads to equivalent levels of visual function after 3 years
4. Is better tolerated by patients

### Overall study start date
01/10/2012

### Completion date
01/10/2020

## Eligibility

### Key inclusion criteria
1. Diagnosis of open angle glaucoma (defined as an open drainage angle and reproducible glaucomatous visual field defects as tested by the SITA algorithm on the Humphrey Visual Field or glaucomatous optic neuropathy)
2. Or ocular hypertension (intra-ocular pressure above 21mmHg and requiring treatment as per NICE Guidelines) with a decision to treat made by a Consultant Glaucoma. Specialist.
3. Age over 18 years
4. Able to provide informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
718

### Total final enrolment

718

### Key exclusion criteria
1. Advanced glaucoma in the potentially eligible eye
2. Secondary glaucoma (e.g. pigment dispersion syndrome, rubeosis, trauma etc) or any angle closure
3. Any contra-indication to selective laser trabeculoplasty (e.g. unable to sit at the laser-mounted slit-lamp; past history of uveitis)
4. Unable to use topical medical therapy due to e.g. physical infirmity and a lack of carers able to administer daily eye-drops
5. Previous treatment for OAG or OHT
6. History of retinal ischaemia, macular oedema or diabetic retinopathy
7. Age-related macular degeneration with neovascularisation or geographic atrophy
8. Any previous intra-ocular surgery, except uncomplicated phaco-emulsification at least one year before.
9. Current pregnancy or intention to become pregnant within the duration of the trial
10. Medically unfit for completion of the trial  e.g. suffering from a terminal illness or too unwell to be able to attend hospital clinic visits
11. Recent involvement in another research study (within 3 months)

### Date of first enrolment
01/10/2012

### Date of final enrolment
01/10/2017

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Moorfields Eye Hospital**
London
United Kingdom
EC1V 2PD

## Sponsor information

### Organisation
Moorfields Eye Hospital (UK)

### Sponsor details

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London
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+44 (0)20 7253 3411
richard.wormald@moorfields.nhs.uk

### Sponsor type
Hospital/treatment centre

### Website
http://www.moorfields.nhs.uk/

### ROR
https://ror.org/03tb37539

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) ref: 09/104/40

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date
31/12/2021

### Individual participant data (IPD) sharing plan
Not provided at time of registration

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Statistical Analysis Plan | statistical analysis plan | 11/11/2015 | | No | No |
| Statistical Analysis Plan | erratum to statistical analysis plan | 11/07/2017 | | No | No |

| | | | | | |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/05/2018 | | Yes | No |
| Results article | pre-results | 01/05/2018 | | Yes | No |
| Results article | results | 13/04/2019 | | Yes | No |
| Other publications | NIHR report | 01/06/2019 | | Yes | No |
| Results article | results | 01/04/2020 | 03/02/2020 | Yes | No |
| Other publications | clinical efficacy, predictors of success, and safety report | 01/09/2019 | 10/03/2020 | Yes | No |
| Other publications | Validation of the RCOphth and UKEGS glaucoma risk stratification tool 'GLAUC-STRAT-fast' | 09/05/2022 | 10/05/2022 | Yes | No |
| Results article | | 16/09/2022 | 20/09/2022 | Yes | No |