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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?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03395535

Protocol serial number
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

Primary study design
Interventional

Study design
Unmasked multi-centre pragmatic randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glaucoma

Interventions
Selective laser trabeculoplasty versus conventional medical therapy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Moorfields Eye Hospital (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

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?
Results article	pre-results	01/05/2018		Yes	No
Results article	results	13/04/2019		Yes	No
Results article	results	01/04/2020	03/02/2020	Yes	No
Results article		16/09/2022	20/09/2022	Yes	No
Protocol article	protocol	01/05/2018		Yes	No
Other publications	NIHR report	01/06/2019		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
Statistical Analysis Plan	statistical analysis plan	11/11/2015		No	No
Statistical Analysis Plan	erratum to statistical analysis plan	11/07/2017		No	No