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A study to assess an automated laser device to treat glaucoma

Submission date 22/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/03/2017	**Overall study status** Completed	
Last Edited 15/07/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Glaucoma is an eye condition where the optic nerve, which connects the eye to the brain, becomes damaged over time. Many cases are caused by increased pressure in the eye (intraocular pressure) due to a build-up of fluid. Glaucoma can result in blindness if left untreated and as such it is extremely important to diagnose and treat the condition. Usually, doctors treat the first symptoms of glaucoma by prescribing eye drops. Unfortunately, there can be side effects associated with the use of these eye drops and there are reports of non-compliance due to difficulties in inserting these drops, all of which can impact on how effective this treatment is. Selective Laser Trabeculoplasty (SLT) is a laser treatment that opens up the drainage tubes inside the eye, allowing more fluid to drain out of the eye, reducing the intraocular pressure and helping to control the progression of the disease. SLT is a technique routinely carried out by glaucoma specialists. It is conducted using a special type of lens (goniolens) that gently sits on the front surface of the eye. The procedure takes about 5 minutes. A new treatment called Direct Selective Laser Trabeculoplasty (DSLT) is performed directly, without there being any need to use a goniolens which sits on the eye. It is a shorter and simpler technique to perform compared to the standard SLT technique. In early studies, it has been shown to have similar pressure reducing abilities to the standard SLT technique. The aim of this study is to assess how well the new automated DSLT device developed by BELKIN Laser Ltd, Israel works in comparison with standard SLT, and determine whether it is as effective at reducing intraocular pressure.

Who can participate?
Patients aged over 40 with mild to moderate open angle glaucoma and ocular hypertension

What does the study involve?
The treating ophthalmologist performs a complete eye examination of each participant. This includes vision assessment, intraocular pressure and visual field measurements, examination of the back of the eyes and a check of the overall health of the eyes. On the eligibility visit, the intraocular pressure is checked and participants are randomly allocated to receive either SLT (the standard treatment) or DSLT (the new treatment). Intraocular pressure is measured after 1 day, 1 week, 1, 3, 6, and 12 months.

What are the possible benefits and risks of participating?
Benefits to taking part in this study include a 50% chance of receiving the new DSLT technique which could result in a speedier treatment, less inflammation and less discomfort during and following treatment. The risks of taking part in the study are the same as those associated with the standard laser procedure, including eye inflammation, discomfort and pressure spikes. Inflammatory reactions can affect either the front (more common) and/or back of the eye (retina – less common). The inflammation is usually mild to moderate and short-lived, usually reducing within 24 hours following treatment and gone within 5 days. Another risk associated with laser trabeculoplasty treatment is pressure spikes after the operation. These usually occur quite soon after the procedure (1-2 hours) and careful patient selection and preventative medication can be given to avoid their occurrence.

Where is the study run from?
1. Queen's University Belfast (UK)
2. The University of Genova (Italy)
3. Moorfields Eye Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2017 to January 2023

Who is funding the study?
BELKIN Laser Ltd

Who is the main contact?
Dr Dorit Raz-Prag, dorit.razprag@alcon.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT03750201

Protocol serial number
GLAUrious-2017-01

Study information

Scientific Title
Direct selective laser trabeculoplasty (DSLT) in open angle glaucoma (OAG): a randomized controlled trial

Acronym
GLAUrious

Study objectives
Direct Selective Laser Trabeculoplasty (DSLT) is not inferior to Selective Laser Trabeculoplasty (SLT) in reducing intraocular pressure (IOP).

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. North West - Greater Manchester West Research Ethics Committee, ref: 17/NW/0358.
2. Regional Ethics Committee- Comitato Etico Regionale della Liguria, IRCCS San Martino, 27/07/2017, ref: 287REG2017

Study design
Randomized controlled masked (investigator(s)) study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Interventions as of 16/11/2018:
Eligible patients who sign the informed consent will be enrolled at each of the study sites, and undergo a washout (in the case of being medicated). After washout there will be a baseline visit, where continued eligibility is confirmed. Following confirmation of continued eligibility, 50% of patients are randomized to each treatment group (DSLT or SLT). Randomization will be to a pre-determined randomization list. The un-masked investigator(s) will open the envelope corresponding to the subject ID and administer the treatment as indicated by the randomization envelope. Only one eye per participant will be included in the study and they will be treated using either DSLT or SLT as per the randomized treatment allocation. The ophthalmologist(s) who perform the follow up (1 day, 1 week, 1, 3, 6, and 12 months) will be masked as to the nature of the treatment the patient underwent.

Previous interventions:
Eligible patients who sign the informed consent will be enrolled at each of the study sites, and undergo a washout (in the case of being medicated). After washout there will be a baseline visit, where continued eligibility is confirmed. Following confirmation of continued eligibility, 50% of patients are randomized to each treatment group (DSLT or SLT). Randomization will be to a pre-determined randomization list. The un-masked investigator(s) will open the envelope corresponding to the subject ID and administer the treatment as indicated by the randomization envelope. Only one eye per participant will be included in the study and they will be treated using either DSLT or SLT as per the randomized treatment allocation. The ophthalmologist(s) who perform the follow up (3, 6, and 12 months) will be masked as to the nature of the treatment the patient underwent.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Primary effectiveness endpoint:
The primary effectiveness endpoint is the difference between the two treatment groups between the mean (washed out for medicated patients) baseline IOP and the mean (washed out for medicated patients) IOP measured at 6 months.
Eligible patients on medications will be washed out at both treatment groups. The mean intraocular pressure (IOP) at baseline before the treatment and washed out IOP at 6 months will

be measured by Goldmann Applanation Tonometry. The difference between the two treatment groups in change between mean washout baseline and 6-month IOP will be estimated.

Safety endpoints:
Adverse events

Key secondary outcome(s))
1. Mean percentage reduction in IOP, measured by Goldmann Applanation Tonometry at 3, 6, and 12 months
2. Number of medications being taken for each eye at baseline (before treatment) and 12 months

Completion date
30/01/2023

Eligibility

Key inclusion criteria
1. Age 40 years or older, with visual acuity > 6/60 in both eyes
2. Primary open-angle glaucoma including exfoliative or pigmentary glaucoma; added 03/06/2020: or ocular hypertension
3. IOP ≥ 22mmHg to ≤35mmHg (in the case of a medicated patient at the baseline visit following washout and in the case of a naïve (newly diagnosed) patient at the time of screening)
4. Gonioscopically visible scleral spur for 360 degrees without indentation
5. Ability to visualize the peri-limbal sclera for 360 degrees (using a speculum)
6. Willing and able to participate in the 12-month study, to comply with the study procedures and to adhere to the follow-up schedule
7. Participant capable of giving informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

Total final enrolment
276

Key exclusion criteria
Individuals with the following characteristics will be excluded from the study (unless specified otherwise, all ocular criteria refer to the study eye only):

1. Contraindications to conventional laser trabeculoplasty (e.g. corneal abnormalities, etc)
2. Angle Closure Glaucoma
3. Congenital or developmental glaucoma
4. Secondary glaucoma except exfoliative or pigmentary glaucoma
5. Presence of any Peripheral Anterior Synechiae (PAS) in the study eye
6. Inability to conduct a reliable visual field (defined as fixation losses, false positives or false negatives greater than 33%)
7. Any of the following visual field findings using the Humphrey visual field analyzer the SITA-standard 24-2 program:
7.1. A visual field MD of less than -12dB
7.2. Greater than or equal to 75% of points depressed below the 5% level and greater than or equal to 50% of points depressed below the 1% level on the PD plot
7.3. At least 50% of points (i.e., 2 or more) within the central 5 degrees with a sensitivity ≤0dB on the decibel plot
7.4. Points within the central 5 degrees of fixation with a sensitivity <15 dB in both hemifields on the decibel plot
8. A visual field MD of less than -12dB in the fellow eye
9. Cup:Disc Ratio of more than 0.8
10. More than two hypotensive mediations required
11. Prior incisional or laser glaucoma surgery
12. Prior corneal refractive surgery
13. Complicated cataract surgery ≤ 6 months prior to enrollment
14. Presence of visually significant cataract in the opinion of the investigator
15. Clinically significant disease in either eye as determined by the Investigator
16. Clinically significant amblyopia in either eye
17. Women who are pregnant or may become pregnant during the course of the study
18. Added 16/03/2018: Dense pigmentation or haemorrhage in the peri-limbal conjunctiva or anterior sclera
19. In the opinion of the investigator the participant might require other ocular surgery within the 12-month follow-up period, unless for further reduction of their IOP
20. Concurrent treatment with topical, nasal, inhaled or systemic steroids
21. Uncontrolled systemic disease that could impact the ability of the participant to attend follow up visits as per the discretion of the investigator

Date of first enrolment
24/10/2018

Date of final enrolment
24/09/2021

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Israel

Italy

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT7 1NN

Study participating centre
The University of Genova (Universita Degli Study Di Genova)
Genova
Italy
16132

Study participating centre
Moorfields Eye Hospital
162 City Road
London
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EC1V 2PD

Study participating centre
Rabin Medical Center
Zeev Jabutinsky Rd 39
Petah Tikva
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49100

Study participating centre
Rambam Medical Center
HaAliya HaShniya St 8
Haifa
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3109601

Sponsor information

Organisation

BELKIN Laser Ltd

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Current Individual participant data (IPD) sharing plan as of 20/02/2024:
There are not current plans to share the datasets. The device is CE marked

Previous Individual participant data (IPD) sharing plan:
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Nathan Congdon

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/05/2025	15/07/2025	Yes	No
Protocol article	protocol	25/08/2021	27/08/2021	Yes	No
HRA research summary			28/06/2023	No	No