

# A study to assess an automated laser device to treat glaucoma

<b>Submission date</b> 22/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/01/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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](mailto:dorit.razprag@alcon.com)

## Contact information

### Type(s)

Public

### Contact name

Dr Dorit Raz-Prag

### Contact details

BELKIN-Vision  
13 Gan Raveh St.  
Yavne  
Israel  
8122214  
+972 (54) 2560197  
[dorit.razprag@alcon.com](mailto:dorit.razprag@alcon.com)

### Type(s)

Scientific

### Contact name

Prof Michael Belkin

### ORCID ID

<http://orcid.org/0000-0002-6174-1182>

**Contact details**

4 Alonim St.  
Givat Shmuel  
Israel  
5404402

**Type(s)**

Scientific

**Contact name**

Prof Nathan Congdon

**ORCID ID**

<http://orcid.org/0000-0001-9866-3416>

**Contact details**

Queen's University Belfast  
Belfast  
United Kingdom  
BT7 1NN

**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

NCT03750201

**Secondary identifying numbers**

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

**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 to request a patient information sheet

**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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/07/2017

## **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  $\geq$  22mmHg to  $\leq$  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

## **Age group**

Adult

**Lower age limit**

40 Years

**Sex**

Both

**Target number of participants**

124

**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  $\leq 0$ dB 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 medications required
11. Prior incisional or laser glaucoma surgery
12. Prior corneal refractive surgery
13. Complicated cataract surgery  $\leq 6$  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**

England

Israel

Italy

Northern Ireland

United Kingdom

**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

United Kingdom

EC1V 2PD

**Study participating centre**

**Rabin Medical Center**

Zeev Jabutinsky Rd 39

Petah Tikva  
Israel  
49100

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

## Sponsor information

**Organisation**  
BELKIN Laser Ltd

**Sponsor details**  
Gan Raveh 13  
Yavne  
Israel  
8122214

**Sponsor type**  
Industry

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Horizon 2020 Framework Programme

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

**Funding Body Type**  
Government organisation



**Funding Body Subtype**  
National government

**Location**

## Results and Publications

**Publication and dissemination plan**  
Planned publication in a high-impact peer reviewed journal

**Intention to publish date**  
15/02/2025

**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?
<a href="#">Protocol article</a>	protocol	25/08/2021	27/08/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No