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GLAUrious long-term follow-up study of glaucoma laser treatment

Submission date 07/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/07/2023	**Overall study status** Completed	
Last Edited 08/08/2023	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
This study will only enroll participants who took part in a study called GLAUrious, conducted between 2018 and 2021. The purpose of the original study was to assess the safety and effectiveness of a new automated direct selective laser trabeculoplasty device (DSLT). Selective Laser Trabeculoplasty (SLT) is a laser-based procedure used to treat open-angle glaucoma. It involves using a low-energy laser to target and stimulate specific cells in the eye's drainage system, improving fluid outflow and reducing intraocular pressure. Unlike other laser treatments, SLT is "selective" and doesn't cause damage to surrounding tissue. By enhancing drainage, SLT helps manage glaucoma and prevent vision loss. It is a safe and effective alternative to medication or surgery, with minimal side effects.

Who can participate?
All participants who were part of the GLAUrious study

What does the study involve?
A one-off visit in which a few assessments, as part of your normal eye care will be conducted. This is so that we can look at the long-term safety with the treatment types looked at in the original study and let us see if there are any differences between them over the long term.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Belkin Vision (Israel)

When is the study starting and how long is it expected to run for?
July 2023 to August 2024

Who is funding the study?
Belkin Vision (Israel)

Who is the main contact?
glauriousltfu@belkin-vision.com

Contact information

Type(s)
Public

Contact name
Dr Clinical Operations Manager

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329958

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CA-PL-01-010, CPMS 57059, IRAS 329958

Study information

Scientific Title
Long-term observational follow-up of participants treated in the GLAUrious trial

Acronym
GLAUrious LTFU

Study objectives
Observational study to assess long term results

Ethics approval required
Ethics approval required

Ethics approval(s)

Not yet submitted

Study design
Observational long-term follow-up

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet
Not available in web format; please use contact details to request a participant information sheet. Study is restricted to the former participants of the original GLAUrious clinical trial.

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

Interventions
Cross sectional, observational study examining participants enrolled to the GLAUrious study having received either SLT or DSLT treatment as part of the randomized controlled trial. Qualified participants will be contacted to ask if they would be willing to participate in an observational follow up study to collect data to assess the long-term safety of participants treated as part of this randomized controlled study. If they agree, they will be asked to attend the clinic for one visit. Participants are expected to be in the clinic for about 3-4 hours. The following clinical assessment will be performed for all study participants in both eyes in this order:
• Medical History
• Ocular history (including details of any secondary surgical intervention, previous contact lens wear and glaucoma medication administration)
• Manifest refraction and BVCA
• Visual field
• Slit lamp examination
• IOP
• Fundus Examination (if BCVA warrants this assessment)

Intervention Type
Other

Primary outcome measure
Safety parameters (slit lamp exam). This observational study includes only one single visit.

Secondary outcome measures
Additional safety parameters (IOP, visual field, and fundus exam). This observational study includes only one single visit.

Overall study start date
07/07/2023

Completion date
01/08/2024

Eligibility

Key inclusion criteria
Participants enrolled to the GLAUrious study and treated with either the SLT or DSLT between November 2018 and May 2021

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
192

Key exclusion criteria
Participants who were not enrolled to the GLAUrious study and treated with either the SLT or DSLT between November 2018 and May 2021

Date of first enrolment
01/08/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
England

Georgia

Israel

Italy

Northern Ireland

United Kingdom

Study participating centre
Clinica Oculistica Università di Genova
Genova
Italy
16132

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT9 7AB

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

Study participating centre
Rabin Medical Center
Petah Tikva
Israel
4941492

Study participating centre
Rambam Health Care Campus
Haifa
Israel
3109601

Study participating centre
Shaare Zedek Medical Center
Jerusalem
Israel
9103102

Study participating centre
Soroka Medical Center
Be'er Sheva
Israel
8457108

Study participating centre
Wolfson Medical Center
Holon
Israel
5822012

Study participating centre
Akhali Mzera
Georgia
0162

Study participating centre
Javrishvili Eye Clinic
Georgia
0159

Study participating centre
Tbilisi State Medical University/ Ingorokva High Medical Technology University Clinic
Georgia
0144

Study participating centre
Hadassah Ein-Kerem
Jerusalem
Israel
91120

Study participating centre
Assuta
Tel-Aviv
Israel
6789140

Study participating centre
Carmel Medical Center
Haifa
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3436212

Sponsor information

Organisation
BELKIN Vision

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Belkin Vision

Results and Publications

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

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date