ISRCTN16769682 https://doi.org/10.1186/ISRCTN16769682

A study aiming at showing the performance and safety of the Eagle device by collecting data from patients being treated for glaucoma or eye hypertension with the Eagle device

Submission date
28/03/2024

Recruitment status
No longer recruiting

Registration date
02/07/2024

Overall study status
Completed

Last Edited
02/08/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is designed to evaluate the performance and safety of the Eagle® device when used within the intended use covered by the CE marking and following the Standard of Care. The Eagle device is a laser device for direct selective laser trabeculoplasty (DSLT) for the treatment of glaucoma. The laser treatment with the Eagle device is performed without the need to use a lens that touches the eye as in the traditional laser treatment. An image processing algorithm automatically localises the target area, which the operator or eye care professional (ECP) readjusts if necessary. Once the operator has confirmed the target area, an eye-tracking system enables the eye movement to be tracked so that the laser pulses are delivered precisely to the target area.

Who can participate?
Patients aged 18 years old and over who underwent treatment with the eagle device for treatment of open-angle glaucoma including exfoliative or pigmentary glaucoma or ocular hypertension as per the approved indication with expected post-operative follow-up data of at least six months

What does the study involve?
This study is a registry designed to evaluate the performance and safety of the Eagle® device when used within the intended use covered by the CE marking and following the Standard of Care. The study will register the information usually collected by your doctor at the time points specified by them. The only requirement is that two doctor visits be recorded so the performance and safety of the treatment with the Eagle device can be evaluated.

What are the possible benefits and risks of participating?
Participants are unlikely to derive any personal health benefits from participating in this study

because the collection of data for the registry is independent of the standard of care decisions made by their doctor. However, the results of the study may help to better assess the treatment of glaucoma in the future.

As only data are collected in the study, participation is not associated with any medical risks beyond the ones related to your medical care as decided and performed by the doctor.

Where is the study run from?
BELKIN Vision Ltd.

When is the study starting and how long is it expected to run for?
August 2023 to December 2025

Who is funding the study?
BELKIN Vision Ltd.

Who is the main contact?
BELKIN Vision: registry@belkin-vision.com
Medevise Consulting: clinicals@medevise-consulting.com

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
337141

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 337141, CPMS 60903

Study information

Scientific Title
An observational, registry-based study of performance and safety data from participants treated for open angle glaucoma or ocular hypertension with the Eagle device

Acronym
BELKIN-PMCF

Study objectives
To assess the mean change from baseline in intraocular pressure (IOP) within the 4-8 months post-treatment interval following the direct selective laser trabeculoplasty treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. submitted 07/03/2023, West Midlands – Edgbaston (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8155, (0)207 104 8357; edgbaston.rec@hra.nhs.uk), ref: None provided

2. approved 27/02/2024, Ethik-Kommission Westfalen-Lippe (Gartenstraße 210–214, Münster, 48147, Germany; +49 (0)251 929-2460; ethik-kommission@aekwl.de), ref: 2024-040-f-S

3. submitted 23/01/2024, Ethisch Comité UZA/UAntwerpen (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 (0)3 821 38 97; ethisch.comite@uza.be), ref: 6219

Study design
Observational

Primary study design
Observational

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Glaucoma and ocular hypertension

Interventions
The purpose of this registry is to evaluate the effectiveness and safety of the Eagle device when used within its designated use as outlined by the CE-marking and in adherence to standard care protocols. The information gathered will aid in the proactive monitoring of device performance and safety, aligning with the post-market surveillance requirements outlined in Regulation (EU) 2017/745.

Initially, participants will undergo direct selective laser trabeculoplasty (DSLT) using the Eagle device to manage the elevated eye pressure associated with their glaucoma. This study seeks to analyze the average change in intraocular pressure (IOP) from baseline for 4-8 months post-treatment.

The primary outcome assesses changes in IOP over time and the secondary outcomes will investigate the performance and safety of Eagle device in adult participants treated for open-angle glaucoma or ocular hypertension.

This is an observational study and the data collection plan is not compulsory but offers a template for data collection depending on the standard of care in force at the site.
The registry data will be collected at the three predefined post-treatment intervals of 0-4 months, 4-8 months and 8-12 months.
When multiple visits occur within a single registry interval, then the latest available assessment taken within the interval is the one collected as part of the registry.

Participants may not have data at all 3 post-treatment intervals.
The following key data points are to be collected for both eyes, if performed by the investigators as part of the standard of care and where applicable the case report form will collect the information on right, left or both eyes, where applicable:
Data collection before DSLT performed with the Eagle device:
- Participant demographics (age and gender)
- Ethnic group of the participant
- Type of glaucoma
- Angle pigmentation
- Number and names of ocular medications at 1st treatment
- Previous procedures

Data collection on the day of standard of care DSLT performed with the Eagle device:
- Date of procedure, baseline IOP, baseline BCDVA, baseline refraction
- Treatment area (180° or 360)
- Laser energy used for treatment on each participant's eye
- Physician's assessment on the usability
- Participant satisfaction after treatment

Data collection after DSLT performed with the Eagle device:
- IOP at each follow-up interval
- Refraction at each follow-up interval (Optional)
- Post-treatment surgical intervention
- BCDVA at each follow-up interval
- Name of ocular medications, if any, at follow-up intervals
- Rates of Adverse Device Effects

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eagle®

Primary outcome(s)
Intraocular pressure (IOP) measured using data collected in medical records at the standard of care timepoint within the 4-8 months post-treatment interval following the direct selective laser trabeculoplasty treatment

Key secondary outcome(s))
1. Performance of the device measured using data collected in patient medical records associated with the evaluation of IOP, potential post-treatment surgical intervention, retreatments with the Eagle device and ocular medication of the participant after treatment at the study end
2. Device safety measured using data collected in patient medical records associated with the rate of adverse device effects and device deficiencies at the study end
3. The usability for the practician measured using a bespoke questionnaire at the direct selective laser trabeculoplasty (DSLT) procedure visit
4. Patient experience measured using a bespoke questionnaire at the DSLT procedure visit

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Adult participants who underwent treatment with the Eagle device for treatment of Open Angle Glaucoma including exfoliative or pigmentary glaucoma or ocular hypertension as per the approved indication.
2. Participants with expected post-operative follow-up data of at least six (6) months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Key exclusion criteria
Records of participants with any of the following conditions at the date of the treatment with the Eagle device, will not be included in the data collection:
1. Participants who are unable to fixate their head and/or eyes, such as participants suffering from nystagmus, tremors or similar conditions.
2. Participants with congenital glaucoma or active anterior segment inflammations.
3. Participants with any condition that obscures the limbus, such as melanosis affecting the limbus, severe arcus senilis affecting the limbus, pterygium affecting the limbus or any other such conditions.
4. Participants with any condition that causes poor visualization of the limbus that prevents the Eagle device’s treatment target identification.

Date of first enrolment

01/05/2024

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Belgium

Germany

Israel

Italy

Study participating centre
Highlands Treatment Centre
Campus
Inversness
United Kingdom
IV2 5NA

Study participating centre
Moorfields Eye Hospital (City Road Campus)
162 City Road
London
United Kingdom
EC1V 2PD

Study participating centre
Shaare Zedek Medical Center
Shmuel (Hans) Beyth St 12
Jerusalem
Israel
9103102

Study participating centre
Vision Medica
Via Salaria, 400
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00199

Study participating centre
Università della Campania, Luigi Vanvitelli
Viale Abramo Lincoln, 5
Caserta CE
Italy
81100

Study participating centre
Oogcentrum Medipolis
Boomsesteenweg 223
Wilrijk
Belgium
2610

Study participating centre
University Eye Clinic
In der Schornau 23-25
Bochum
Germany
44892

Sponsor information

Organisation
BELKIN Vision Ltd.

Funder(s)

Funder type
Industry

Funder Name
BELKIN Vision Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
All personal registry subject data collected and processed for this registry will be maintained with adequate precautions to ensure the confidentiality of the data according to local, state, and federal laws and regulations. Data is pseudonymized and extracted, analysed, validated and reported in aggregate to prevent any potential that any investigator will access individual participant data in which the participant may be identified during data compilation, data reporting or data analysis. A report of the results of this registry may be published or sent to the appropriate health authorities in any country in which the registry device may be marketed, but the subject's identity will not be disclosed in these documents.

The online registry must be kept up-to-date so that it always reflects the latest observations on the participants enrolled in the clinical investigation. The online software OpenClinica and OpenClinica Insight will be used as the data registry. Data can be entered online, directly on the registry by the practician, after an independently planned interval following treatment with the Eagle device. The handling of all data on the Case Report Forms/registry questionnaires will be the responsibility of BELKIN Vision or their delegated representative.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes