ISRCTN96192007 https://doi.org/10.1186/ISRCTN96192007

Assessing the efficacy and safety of a recently introduced type of surgical device (Preserflo Microshunt) in the treatment of glaucoma

Submission date
19/09/2021

Recruitment status
No longer recruiting

Registration date
11/10/2021

Overall study status
Completed

Last Edited
11/10/2021

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
Glaucoma is a common eye disease affecting the optic nerve and leading to irreversible blindness. This disease is thought to be caused by excess pressure inside the eye. The Preserflo Microshunt is a device similar to a tube that is implanted in the front part of the eye and allows for the drainage of fluid from the eye, relieving the pressure. The aim of this study is to determine how effective is this surgery, if it effectively lowers the pressure in the long term, if it relieves the burden of eye drops in glaucoma patients, and if it is a safe surgical option.

Who can participate?
Data is extracted from patient files of any adult patient with glaucoma who has been implanted with the Preserflo Microshunt between June 2019 and September 2021 at the Hospital de Santa Maria, Centro Hospitalar e Universitário Lisboa Norte

What does the study involve?
The investigators will examine the patient charts to analyze if the surgery effectively reduced eye pressure in a safe manner throughout the patients' follow-up time.

What are the possible benefits and risks of participating?
None as this is a retrospective study

Where is the study run from?
Hospital de Santa Maria, Centro Hospitalar e Universitário Lisboa Norte (Portugal)

When is the study starting and how long is it expected to run for?
May 2019 to December 2021

Who is funding the study?
Universidade de Lisboa (Portugal)

Who is the main contact?
Rafael Barão
rafaelcbarao@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Rafael Barão

ORCID ID
http://orcid.org/0000-0002-3102-1969

Contact details
Av. Prof. Egas Moniz
Lisbon
Portugal
1649-035
+351 (0)916316796
rafael.barao@chln.min-saude.pt

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Early clinical outcomes of the Preserflo Microshunt

Study objectives
To assess the efficacy (hypotensive power) and safety (rate of complications) of the Preserflo Microshunt, an aqueous drainage shunt aimed for the treatment of medically uncontrolled glaucoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, North Lisbon University Hospital (CHUL) and Lisbon Academic Center (CAML) Ethics Committee (Av. Prof. Egas Moniz, 1649-035 Lisboa; +351 (0)217805405; anapimentel@chln.min-saude.pt)

Study design
Single-center cross sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

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
Intraocular pressure control in patients with glaucoma

Interventions
Data is extracted from patient files (background history, glaucoma characteristics, baseline intraocular pressure [IOP], preoperative visual acuity [VA], number of ocular hypotensive medication, intra-operative and postoperative complications, follow-up from visits on day 1; at weeks 1, 4; at months 3, 6 and 12 after Preserflo Microshunt implantation; number of postoperative IOP-lowering medication at all timepoints; and previous or subsequent surgical interventions).

Intervention Type
Procedure/Surgery

Primary outcome measure
The surgical success of Preserflo Microshunt implantation at 12 months postoperative, defined as at least 30% reduction in IOP from baseline and final IOP ≤18mmHg and >5 mmHg, with (qualified success) or without hypotensive drugs (absolute success)

Secondary outcome measures
1. Mean IOP in mmHg measured using Goldmann applanation tonometry and retrieved from patient files at the last pre-operative visit and at day 1, day 7, months 1, 3, 6, 12, 18 and 24 postoperative (when respectively applicable)
2. Mean number of hypotensive drugs retrieved from patient files at the last pre-operative visit

and at day 1, day 7, months 1, 3, 6, 12, 18 and 24 postoperative (when respectively applicable)
3. Intra-operative or postoperative complications retrieved from patient files at time of surgery, day 1, day 7, months 1, 3, 6, 12, 18 and 24 (when respectively applicable)

Overall study start date
01/05/2021

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Patients submitted to Preserflo Microshunt implantation for medically uncontrolled glaucoma between June 2019 and September 2021
2. Age ≥18 years and have agreed to chart review as per GDPR regulations

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Severe cardiovascular disease (including a stroke or a myocardial infarction 6 months before)
3. Known allergic reaction to MMC

Date of first enrolment
01/06/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Portugal

Study participating centre
Hospital de Santa Maria, Centro Hospitalar e Universitário Lisboa Norte
Av. Prof. Egas Moniz
Lisbon
Portugal
1649-035

Sponsor information

Organisation
Centro Hospitalar Lisboa Norte

Sponsor details
Av. Prof. Egas Moniz
Lisbon
Portugal
1649-028
+351 (0)217805000
walter.rodrigues@chln.min-saude.pt

Sponsor type
Hospital/treatment centre

Website
http://www.chln.min-saude.pt/

ROR
https://ror.org/020sr6z07

Funder(s)

Funder type
University/education

Funder Name
Universidade de Lisboa

Alternative Name(s)
Universitas Olisiponensis, University of Lisbon, Technical University of Lisbon, ULisboa | Universidade de Lisboa, University of Lisbon, Portugal, New University of Lisbon (Portugal), ULisboa

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Portugal

Results and Publications

Publication and dissemination plan
The results of this study should be published in a high-visibility peer-reviewed journal.

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from any investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose, exclusively for individual participant data meta-analysis. Data requests should be addressed to Rafael Barão (rafael.barao@chln.min-saude.pt). Data willing to be shared will include relevant individual participant data that underlie the results reported in this article, after deidentification and anonymisation. Data requests may be submitted from 6 months to up to 24 months following article publication. Use of this data has been included in the patient consent form.

IPD sharing plan summary
Available on request