ISRCTN93098069 https://doi.org/10.1186/ISRCTN93098069

To analyze surgical success comparing a single medication (antifibrotic drug) with double medication (same antifibrotic plus antiproliferative drug) in trabeculectomy (filtrating surgery to decrease intraocular pressure in glaucoma patients)

Submission date	Recruitment status	[_] Prospectively registered
07/04/2020	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
15/04/2020	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
05/05/2021	Surgery	

Plain English summary of protocol

Background and study aims
Glaucoma is a common eye condition where the optic nerve, which connects the eye to the brain, becomes damaged. It's usually caused by fluid building up in the front part of the eye, which increases pressure inside the eye.
Trabeculectomy is a surgical operation which lowers the intraocular pressure inside the eye (IOP) in patients with glaucoma. This is achieved by making a small hole in the eye wall (sclera). Avoiding excessive wound healing response remains a problem, once surgery success depends on maintaining patency of the fistula and bleb filtration. Antiproliferative agents such as mitomycin C (MMC) reduce inflammation and scarring process, improving surgical outcome. However, besides the high risk of potentially complications, studies have not proven to be fully satisfactory and new therapeutic approaches more effective and safer are currently been used to augment surgery. The use of antiangiogenic factors (such as bevacizumab) has been associated with slowing this proliferative and fibrotic process after filtration surgery.
The study aims to explore this promising modality to understand if bevacizumab is an important additional agent in improving the prognosis of glaucoma filtrating surgery.

Who can participate?, What does the study involve?
Data is extracted from medical charts of patients submitted to primary trabeculectomy for open-angle glaucoma at Centro Hospitalar Universitário Lisboa Norte and Hospital dos Lusíadas between October 2015 and March 2019

What are the possible benefits and risks of participating?
None (retrospective study)

Where is the study run from?
1. Centro Hospitalar Universitário Lisboa Norte (Portugal)
2. Hospital dos Lusíadas (Portugal)

When is the study starting and how long is it expected to run for?
September 2019 to May 2020

Who is funding the study?
Centro de Estudos das Ciências da Visão - Faculdade de Medicina da Universidade de Lisboa

Who is the main contact?
Dr Patrícia José, patricialopes1@campus.ul.pt

Contact information

Type(s)
Public

Contact name
Dr Patrícia José

ORCID ID
http://orcid.org/0000-0002-4523-7306

Contact details
Centro Hospitalar Universitário Lisboa Norte
Av. Prof. Egas Moniz
Lisbon
Portugal
1649-035
+351 964958859
patricialopes1@campus.ul.pt

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20031992

Study information

Scientific Title

Trabeculectomy with mitomycin C or with mitomycin C plus intracameral bevacizumab injection? A comparative study

Study objectives
To analyze the benefits of using intracameral bevacizumab injection as an add on to the standard of care use of mitomycin C (MMC) in trabeculectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2019, Ethics Committee of Centro Hospitalar Universitário Lisboa Norte and Hospital dos Lusíadas (R. Abílio Mendes, 1500-458, Lisbon, Portugal; +351 966 184 461; knowledgecenter@lusiadas.pt), ref: n/a

Study design
Observational cross-sectional cohort 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 below to request a patient information sheet.

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

Interventions
Data is extracted from medical charts (background history, glaucoma characteristics, baseline IOP, preoperative visual acuity, number of ocular hypotensive medication, safety parameters, follow-up from visits on day 1; at weeks 1, 4; at months 3, 6, 12 and 24 after trabeculectomy, number of postoperative IOP-lowering medication and surgical interventions). All consecutive patients from one site (Centro Hospitalar Universitário Lisboa Norte) received standard of care; all consecutive patients from the second site (Hospital dos Lusíadas) received the becavizumab as an add on to standard of care. Statistical analysis is carried out using SPSS software (Chicago, IL, version 24.0).

Intervention Type
Procedure/Surgery

Primary outcome measure
The absolute and qualified surgical success rate of trabeculectomy at 12 months and 24 months defined as intraocular pressure ≤18 mmHg and >5mmHg with at least 30% reduction in IOP from baseline

Secondary outcome measures
1. Intra- and postoperative complications measured using patient records
2. Additional effects of bevacizumab measured using patient records

Overall study start date
01/09/2019

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Patients submitted to primary trabeculectomy for open-angle glaucoma between October 2015 and March 2019
2. No other previous surgeries, except uncomplicated phaco
3. ≥ 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
Review of entire set of patients within the time range (128 patients assessed for study)

Total final enrolment
128

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Combination with cataract surgery
3. History of another eye disease
4. Uncontrolled blood pressure (systolic >180 mmHg and/or diastolic >100 mmHg while a patient is at rest)
5. Severe cardiovascular disease (including a stroke or a myocardial infarction 6 months before)
6. Known allergic reaction to bevacizumab or MMC

Date of first enrolment
01/10/2015

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Portugal

Study participating centre
Centro Hospitalar Universitário Lisboa Norte
Av. Prof. Egas Moniz
Lisbon
Portugal
1649-028

Study participating centre
Hospital dos Lusíadas
R. Abílio Mendes 12
Lisbon
Portugal
1500-258

Sponsor information

Organisation
Centro Hospitalar Lisboa Norte

Sponsor details
Hospital Lusíadas
Av. Prof Egas Moniz
Lisbon
Portugal
1649-028
+351 962958859
patricialopes1@campus.ul.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
31/12/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/04/2021	05/05/2021	Yes	No