

# 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)

<b>Submission date</b> 07/04/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/05/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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](mailto:patricialopes1@campus.ul.pt)

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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 bevacizumab 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(s)**

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

## **Key secondary outcome(s)**

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

## **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.  $\geq 18$  years and have agreed to chart review as per GDPR regulations

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

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Portugal

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## Sponsor information

**Organisation**

Centro Hospitalar Lisboa Norte

**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

## 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?
<a href="#">Results article</a>		30/04/2021	05/05/2021	Yes	No