

# New techniques for reducing intraocular pressure spike after intravitreal injection of bevacizumab

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<b>Registration date</b> 24/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2023	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The increase in intraocular pressure recorded following intravitreal injection generally resolves without special treatments.

However, up to 5% of patients develop a sustained ocular hypertonus which causes potential permanent damage to the optic nerve,

making it necessary to start or implement a hypotonic therapy. Given this, it is essential to do everything possible to ensure that the post-injection IOP is controlled.

A modality that is recently meeting the attention of the ophthalmological community is represented by the external application of pressure on the eyeball through ocular massage or scleral indentation with cotton swabs before performing the intravitreal injection. The rationale is that the compression of the vitreous volume and therefore of the intraocular volume is capable of determining a consequent reduction in intraocular pressure. Our idea is that these techniques can be really effective in reducing the post-injection pressure spike of antiVEGF substances whether they are applied as a preparation for injection, or if applied afterwards since their rationale is extendable to both pre-injection and post-injection. The aim of our study is to evaluate the effect of various intravitreal injection protocols on post-treatment intraocular pressure of subjects undergoing intravitreal injection of bevacizumab. In particular, scleral indentation using cotton swabs and digital ocular massage performed immediately before or immediately after the intravitreal injection will be analyzed, compared with the "classic" injective protocol.

### Who can participate?

All patients with indication for intravitreal injection of anti-VEGF (vascular endothelial growth factor) drug (bevacizumab)

### What does the study involve?

200 patients (200 total eyes) are enrolled among those who present an indication for the intravitreal injection of bevacizumab drug.

They underwent preoperative eye evaluation and then randomized to the different study arms (40 eyes injected for each study arm), which differ in the injective protocol used: in Arm A,

patients are subjected to the "classic" injective protocol currently in use at our center; patients included in arms B and C underwent intravitreal injection preceded respectively by scleral indentation with cotton swabs (slight external pressure applied to the eyeball with cotton swab) and digital ocular massage; patients included in arms D and E underwent IVT followed respectively by scleral indentation with cotton swabs and digital ocular massage. All patients underwent Goldmann applanation tonometry using sterile and disposable cones before the injective treatment and 10 minutes after the same.

What are the possible benefits and risks of participating?

The acquisition of greater scientific knowledge regarding the impact on intraocular pressure values of different intravitreal injection protocols, in order to identify techniques that are associated with a lower increase in post-treatment pressure and therefore safer for the patient. There are no reasonably foreseeable adverse events arising from participation in the study. The execution of Goldmann applanation tonometry (performed by means of sterile and single-cone cones), scleral indentation and ocular massage do not present particular risks to those of the classical intravitreal injection surgical procedure, well reported in the informed consent for intravitreal injections drawn up by the Italian Ophthalmological Society, which in our center each patient signs before any intravitreal injective treatment, independently of the participation in our study.

Where is the study run from?

A.O.U. Città della Salute e della Scienza, Eye Clinic, University of Turin

When is the study starting and how long is it expected to run for?

March 2019 to May 2019

Who is funding the study?

Università degli Studi di Torino (University of Turin)

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

CS2/966

## Study information

### Scientific Title

Reduction of intraocular pressure spike post intravitreal injection of bevacizumab by scleral indentation with cotton swab or digital ocular massage: innovative techniques compared.

### Study objectives

This study aims to evaluate the effectiveness of each technique compared to the classic injection technique and to compare the various innovative techniques between them, following the intravitreal injection of bevacizumab.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 19/12/2018, Intercompany Ethics Committee of A.O.U. Città della Salute e della Scienza (University of Turin, Via Cherasco 23, Turin, 10126, Italy; +39(0)116336547; comitatoetico@cittadellasalute.to.it) ref: #CS2/966

### Study design

Monocentric prospective non-pharmacological interventional study

### Primary study design

Interventional

### Study type(s)

Treatment

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

Intraocular pressure after bevacizumab intravitreal injection

### Interventions

200 patients were enrolled and underwent preoperative ophthalmologic evaluation, with anamnestic data collection. They were randomized to the different study arms (40 eyes injected for each study arm) using a simple randomisation method.

Arm A was injected by standard intravitreal injection technique, that consists in these steps:

1. Periocular and palpebral skin disinfection with 5% povidone-iodine solution;

2. Topical anesthetic and 5% povidone-iodine instillation in the eye to be injected;
3. Intravitreal injection;
4. Application of gentle pressure using cotton swab for 5 seconds to avoid vitreous reflux
5. Instillation of povidone-iodine 0.5%, Ofloxacin (Oftraquix®) and Netilmicin- Dexamethasone (Netildex®).

Arm B was injected by pre-injection scleral indentation technique (intravitreal injection performed according to the standard protocol, with the addition of pre-injection scleral indentation, that consist in the application of a slight pressure using a cotton swab, such as to induce a minimum folding of the cotton swab rod, directly on the injection site for 60 seconds before performing the intravitreal injection); Arm C was injected by pre-injection digital ocular massage technique (intravitreal injection performed according to the standard protocol, preceded by digital ocular massage for 5 minutes); Arm D was injected by post- injection scleral indentation technique (intravitreal injection performed according to the standard protocol, with addition of post- intravitreal injection scleral indentation); Arm E was injected by post- injection digital ocular massage technique (intravitreal injection performed according to the standard protocol, followed by digital ocular massage).

All subjects underwent Goldmann applanation tonometry 10 min before and 10 min after the intravitreal injection of Bevacizumab.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Variation of the post-injection IOP with the different injection techniques measured using Goldmann applanation tonometry 10 min before and 10 min after injection.

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

1. Percentage of post- intravitreal injection IOP spikes with IOP  $\geq$ 40 mmHg in study arms measured using Goldmann applanation tonometry 10 min before and 10 min after injection
2. Phakia/pseudophakia status
3. Previous diagnosis of glaucoma
4. Ophthalmic pathology for which indication was given to intravitreal injection
5. The percentage of adverse events was also evaluated

### **Completion date**

31/05/2019

## **Eligibility**

### **Key inclusion criteria**

1. Age between 18 to 99 years old
2. Indication for intravitreal injection of anti-VEGF drug (bevacizumab)
3. Absence of contraindications to the execution of intravitreal injection (systemic or local conditions that make the injective treatment not indicated)
4. Possibility of expressing informed consent to participation in the study

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Prior intravitreal injection into the eye being studied in the previous month
2. Prior history of endophthalmitis following intravitreal injection
3. Prior intravitreal steroid injection in the previous 6 months

**Date of first enrolment**

20/03/2019

**Date of final enrolment**

15/05/2019

**Locations****Countries of recruitment**

Italy

**Study participating centre**

A.O.U. Città della Salute e della Scienza, Eye Clinic, University of Turin

Via Cherasco 23

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10126

**Sponsor information****Organisation**

Eye Clinic, University of Turin

**ROR**

<https://ror.org/048tbm396>

**Funder(s)****Funder type**

University/education

**Funder Name**

Università degli Studi di Torino

**Alternative Name(s)**

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Italy

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		07/07/2020	18/08/2023	Yes	No