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

Submission date
02/06/2019

Recruitment status
No longer recruiting

Registration date
24/07/2019

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 rational 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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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

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

Secondary outcome measures
1. Percentage of post- intravitreal injection IOP spikes with IOP ≥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

Overall study start date
19/03/2019

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

Age group
Mixed

Sex
Both

Target number of participants
200 (40 partecipants for each arm)

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
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Sponsor information

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Sponsor type
University/education

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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal one year after the end date of the overall test.

Intention to publish date
01/07/2019

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?
Results article		07/07/2020	18/08/2023	Yes	No