**Study Title**

Ideal Timing of Subconjunctival Anaesthesia before lntravitreal Injection Treatment

**Study Investigator(s)**

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1. **Introduction**

At CDHB, we routinely provide 2% lignocaine subconjunctival injection for anaesthesia prior to deliver intravitreal injection treatment. The guideline currently recommends a minimum waiting time of 2 minutes but often in real life this waiting time varies significantly (usually from 2 to 6 minutes). Some question whether having a longer interval period between the two injections provides better pain control to patients. However no robust study has been conducted to confirm this hypothesis. Here I propose that we should conduct a study looking at the potential association between the waiting time after subconjunctival anaesthesia and the patient perception of pain during the intravitreal injection procedure.

**2. Background**

Intravitreal injection treatment, mainly anti-vascular endothelial growth factor, has become the mainstream treatment for multiple ophthalmic conditions. In CDHB, we provide about 80-100 intravitreal injections per week. In order to reduce discomfort during the intravitreal injection process, we routinely provide 2% lignocaine subconjunctival injection for anaesthesia prior to deliver intravitreal injection treatment.

The CDHB guideline currently recommends a minimum waiting time of 2 minutes before delivering intravitreal injection. However often in real life this waiting time varies significantly (usually from 2 to 6 minutes). Some question whether having a longer interval period between the two injections provides better pain control to patients while others believe that no such association exists. However no robust study has been conducted to test this hypothesis.

Here I propose that we should conduct a study looking at the potential association between the waiting time after subconjunctival anaesthesia and the patient perception of pain during the intravitreal injection procedure.

The study population will be all patients enrolled in intravitreal injection clinics who do not have reduced cognitive function or communication difficulty. We are aiming to get a sample size of 200-300 cases.

**3. Aim(s) of Study**

To find out whether longer waiting time after subconjunctival anesthesia provides better pain control during intravitreal injection procedure.

**4. Objectives**

The objective of this study is to determine if longer waiting time post subconjunctival anaesthesia provides better pain control for patients during intravitreal injection procedure.

**5. Hypothesis**

**Primary Hypothesis**

Pain level experienced by participants during intravitreal injection procedure decreases with longer waiting time after subconjunctival anesthesia.

**6. Study Design**

Randomised controlled study – single blinded.

**7. Study Setting/ Location**

Injection Clinic in Eye Clinic, Canterbury District Health Board.

**8. Study Population**

Population the subjects will be drawn from: all patients who are currently enrolled to receive intravitreal injection treatment through Injection Clinic in CDHB. Aim is to recruit approximately 240 participants and divide the group into 4 subgroups (different waiting time post subconjunctival anesthesia). Each subgroup will have approximately 60 participants.

**9. Eligibility Criteria**

Inclusion and exclusion criteria are standards that you have set determining whether a person may or may not be allowed to enter your study. They are used to identify appropriate participants and to ensure their safety.

**9a. Inclusion criteria**

All patients who are currently enrolled to receive intravitreal injection treatment through Injection Clinic in CDHB.

**9b. Exclusion criteria**

Those who have reduced cognitive function or communication difficulty (i.e. language barrier) will be excluded from the study to avoid potential errors

**10. Study Outcomes**

**10a. Primary Outcome**

Pain/discomfort level during intravitreal injection procedure. This will be measured by visual analogue scale with numerical values (1-10).

**10b. Secondary Outcome(s)**

Participants happy to receive the future intravitreal injection with such level of discomfort – Yes or No.

**11. Study Procedures**

**11a. Recruitment of participants**

All eligible patients who present to Injection Clinic in CDHB will be approached and asked if they would like to participate in this study. Verbal explanation and consent as well as written explanation and consent (on the questionnaire form) will be obtained. We currently inject approximately 40 patients per week so I anticipate that we will be able to complete the recruitment within the next 6 weeks.

**11b. Randomisation**

Sample population will be divided into 4 subgroups (waiting time of 2, 3, 4, and 5 minutes). Randomisation will be obtained by asking participants to draw a random number out of a bag. The number will not be shown to the participants. Only investigator (injector) will be aware of the number. This is to reduce potential bias. The study will be single blinded.

**11c. Study procedure**

Once participants agree to participate in this study, we carry out the injection procedure following current CDHB’s guideline. The two main differences are:

1. Investigators will time themselves and give intravitreal injection after the certain waiting time (dictated by the number each participant has drawn out from the bag). Minimum waiting time is 2 minutes, which complies with the current CDHB recommendation.
2. Participants will be asked to answer 3 simple questions at the end of the procedure.
3. Investigators will complete the staff section on the questionnaire to obtain basic demographic information.

You should include precise details of the treatment(s)/intervention(s) intended for each group/participant. You should also provide details of any follow-up schedule (i.e. time between visits) and consider how you will monitor participants’ adherence with the treatment schedule. You might also describe under which circumstances participants may be withdrawn and how this will occur. A schematic diagram or flow chart may be useful for this section.

**11d. Measurement tools used**

Patient questionnaire will be used. This will be provided to the participants at the end of the procedure.

**11e. Safety considerations/Patient safety**

No safety concern or additional risks to the participants are expected from this study.

**12. Statistical Considerations and Data Analysis**

**12a. Sample size and statistical power**

No power calculation has been performed for this study as no previous study (on the similar subject) has been conducted. However we thought that the sample size of 200-300 will be a good start and we could use this information as a pilot study even if we do not find a statistically significant finding.

**13. Ethical Considerations**

I declare that the study will be conducted in full conformation with principles of the Declaration of Helsinki, Good Clnical Practice and within the laws and regulations of the New Zealand.

**14. Outcomes and Significance**

Although we provide subconjunctival anesthetic injection prior, there is no evidence available to guide clinicians on how long to wait. Therefore there is a significant variations in this waiting time. CDHB recommends a minimum waiting time of 2 minutes but many clinicians wait longer (often up to 6 minutes). This may increase the procedure time unnecessarily. However, if no adequate pain control has been achieved after 2 minutes, then we could be putting patients through unnecessary discomfort. Finding an association between the two factors can help us achieve an efficient service delivery while keeping high quality of patient care.