

## **Subconjunctival Injection of Local Anesthetic in Anterior Blepharoptosis Repair: Study Protocol and Statistical Analysis**

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Status: Recruiting

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Study Start Date: September 1st, 2017

Anticipated Completion Date: March 2020

Sponsor: The University of Manitoba

Ethics Approval: The University of Manitoba Bannatyne Campus Biomedical Research Ethics Board. Affiliated with the University of Manitoba. Approval Number: HS20066 (B2016:085). Address: P126, Pathology Building, 770 Bannatyne Ave., University of Manitoba, Winnipeg, Manitoba, Canada. R3E 0W3.

Study Design: Single group interventional study. Randomized allocation. 100 participants anticipated (200 eyes). Patients to receive two subconjunctival injections each (one to each eye), giving two study arms (intervention vs. sham).

Participants will be recruited from Dr. Lee-Wing's patient population. They will include those who have elected to undergo bilateral ptosis repair and participate in the study. They must meet the following inclusion criteria in order to be deemed eligible to participate:

1. Age over 18 and able to provide informed consent in English.
2. Must have bilateral blepharoptosis undergoing repair using an anterior approach.
3. The degree of ptosis must be approximately symmetrical, with a difference in "Margin Reflex Distance one (the distance between the pupillary light reflex and the margin of the upper lid)" of 1 mm or less between the two sides.

Participants will be excluded if they meet the following criteria:

1. Previous eyelid surgery or trauma.
2. Have congenital, mechanical, myogenic, or neurogenic form of ptosis.
3. Bleeding disorder or inability to discontinue anti-coagulants pre-operatively.
4. Cognitive impairment

After learning about the risks and benefits of participation, each patient will sign an informed consent form on the day of their surgery. Each patient will then receive an intra-operative posterior subconjunctival injection in both eyes. One injection will contain xylocaine (a local anesthetic) while the other will contain normal saline (a sham injection). All surgeries will be performed by Dr. Lee-Wing. Both the participants as well as Dr. Lee-Wing will be blinded as to which eye receives the intervention and the sham injection.

Post-operatively, patients will be asked to complete a pain scale questionnaire immediately following their surgery. Specifically, they will be asked to compare their pain in each eye. The results of this assessment will be compared using McNemar's Test, and will constitute the primary outcome of the study. The secondary outcomes will include:

1. The presence or absence of post-operative lagophthalmos/fluorescein staining, as assessed at the post-operative follow-up. Comparison between the xylocaine injection group and the normal saline injection group will be performed using McNemar's Test.
2. Post-operative "Margin Reflex Distance One" (as described above) will be compared between the xylocaine injection group and the normal saline injection group. The difference between the two groups will be evaluated using a Paired Student's T-Test.

Surgical procedures will be performed at the Buhler Eye Care Centre, Misericordia Hospital, 99 Cornish Ave., Winnipeg, Manitoba, Canada, R3C 1A2.

Data will be intermittently reviewed by Dr. Lee-Wing throughout the study period.

This study has received Ethics Approval from the University of Manitoba: HS20066 (B2016:085).

**Statistical Analysis Plan:**

Data will be collected by means of a written questionnaire, which will be administered post-operatively (see above). Clinical data such as the presence of post-operative lagophthalmos as well as MRD 1 will be entered into Dr. Lee-Wing's medical record system. Data will be stored in Dr. Lee-Wing's office in a locked cabinet, or securely on Dr. Lee-Wing's electronic patient record system.

Data will be anonymized and compiled in spreadsheet format, then analyzed using available statistical analysis programs (to be determined, based on availability at the University).

The post-operative pain ratings between the eyes that receive the xylocaine subconjunctival injection and the eyes that receive the sham injections will be compared using McNemar's Test (IE chi-squared testing). This categorical pain scale may be converted to a continuous variable by assigning a number to each potential response (for instance, a response of "Very Poor" could be assigned a low numerical value whereas a response of "Very Good" would be assigned a high numerical value). The resulting data would be compared using a Paired Student T-Test.

The presence of post-operative lagophthalmos/fluorescein staining will be compared between the experimental and sham injection group using McNemar's Test.

The post-operative MRD 1 will be compared between the two groups using a Paired Student's T-Test.