Hallux Valgus Study using the Bosch Procedure

Dear participant,

Thank you for considering taking part in our study.

Bunions remain a common orthopedic problem for which surgical treatment may be performed but can involve significant postoperative pain.

For this type of surgery, our center uses ultrasound-guided ankle blocks to freeze the nerves around the foot and reduce the amount of pain for 24 to 36 hours following the procedure. However, once the effects of the ankle block have disappeared, patients may still need to use strong pain medication such as morphine or dilaudid. These medications have side effects, such as drowsiness, nausea, vomiting, and constipation and in some cases can result in addiction.

The purpose of this project is to investigate whether the use of multimodal anesthesia (a combination of different types of non-narcotic medications) can reduce or eliminate the use of narcotic drugs such as morphine and dilaudid.

To do this, we will compare a group of patients who will receive the standard medications given prior to bunion surgery (acetaminophen and naprosyn) with a group that will receive the standard medications as well as pregabalin (a common medication used before joint replacement procedures) and ralivia (a long-acting pain medication). If there is still significant pain, then tramadol (a non-narcotic pain medication) or dilaudid can still be used as needed.

For this research project, we intend to recruit 160 participants aged 18 to 70. Of these 160 participants, 80 participants will be in the narcotics-free group and 80 participants will be in the standard group.

This research project will take place at Verdun Hospital, St Mary's Hospital and LaSalle General Hospital. Your participation in this project will last 7 days. During your participation, you will be asked to complete a pain diary and participate in two 5-minute interviews by phone. You will also be asked to fill out some brief questionnaires and to wear a fit-bit type watch in order to track your ability to walk around and sleep well for the week following your procedure.

By participating in this research project, you will be divided into one of the following groups:

- Group 1: Narcotic-Free Drugs Treatment Group Under Study
- Group 2: Narcotic Drugs Standard Treatment Group

Patients who are already taking chronic pain medications will not be eligible to participate in the study.

All participants will be required to fill out a short pain diary (that we will provide) at 6 hours, 12 hours, 24 hours, 36 hours, 48 hours, 72 hours and 7 days after the operation. About one to two minutes will be needed to complete this log. A member of the research team will also call you to complete an interview of less than 5 minutes at 24 and 48 hours after the procedure.

Should you choose to participate you will have a consultation with one of the physicians who will explain the study and procedures in further detail. If you are interested in participating or would like further information, please contact the research co-ordinator at this email: sandhya.baskaran.comtl@ssss.gouv.qc.ca.

Thanks again for your consideration.