Optimizing pain management: A pilot randomized trial in patients undergoing arthroscopic shoulder surgery

Dear participant,

Thank you for considering taking part in our study.

Postoperative pain (POP) affects quality of life, causes psychological distress, and increases the risk of persistent chronic pain. Poorly managed POP imposes a substantial economic burden on patients and Canada's health care system. A 2016 review concluded that more randomized controlled trials (RCT) are needed to evaluate multimodal analgesia (MMA) approaches to POP. Within an MMA regimen, opioids are common and have the highest profile for adverse effects. Opioid reduction strategies for POP management often include a brachial plexus nerve block (BPB), acetaminophen, and a non-steroidal anti-inflammatory drug.

In view of the urgent need to find an effective non-opioid medication regimen as an alternative strategy to decrease opioid use and provide effective POP management, the overall objective of this pilot RCT is to test the feasibility and methods to help plan a future definitive pragmatic 3-arm RCT.

In this multicentre study, 36 patients undergoing arthroscopic surgery for shoulder rotator cuff pathology or shoulder instability will be randomly assigned to a:

- PMC (Pre-surgery medication cocktail pregabalin and celecoxib),
- PMC + Block (Pre-surgery medication cocktail plus interscalene nerve block), or
- Block (Interscalene nerve block).

Questionnaires will be completed before surgery, 6 hours, and at 1 day, 1 week, 2 and 6 months after surgery.

Eligible participants must meet all the following criteria:

Please read all questions carefully and respond by placing a check (✓) in the "YES", "NO" or "Do not know" box.

Table 1. Inclusion criteria:	**Responses**		
	No	**Yes**	**Do not know**
Are you between 18 – 64 years of age?			
Are you having arthroscopic surgery for shoulder rotator cuff pathology or shoulder instability?			
Have you had symptoms for at least 6 months?			
Can you be contacted by telephone?			
Are you willing to comply with all study procedures and be available for the duration of the study?			
Have you signed and dated your informed consent form?			

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Do you understand English or French?			

Please read all questions carefully and respond by placing a check (✓) in the "YES", "NO" or "Do not know" box.			
Table 2. Exclusion criteria:	**Responses**		
	No	**Yes**	**Do not know**
Allergies: do you have an/any allergy to			
Pregabalin?			
Celecoxib and naproxen extended release?			
Ropivacaine and bupivacaine?			
Sulfonamides?			
Health conditions			
Have you taken prednisone, a steroid medication in the past year?			

Please review the following exclusion criteria:

Please read all questions carefully and respond by placing a check (✓) in the "YES", "NO" or "Do not know" box.			
Table 2. Exclusion criteria:	**Responses**		
	No	**Yes**	**Do not know**
Do you have history of asthma, urticaria, or allergic-type reactions after taking Acetylsalicylic Acid (ASA) or other NSAIDs (i.e. complete or partial syndrome of ASA-intolerance-rhinosinusitis, urticaria/angioedema, nasal polyps, asthma)?			
Do you have chronic obstructive pulmonary disease (COPD), bronchitis or emphysema?			
Have you ever had cerebrovascular disease (including but NOT limited to stroke, cerebrovascular accident, transient ischemic attacks and/or amaurosis fugax)?			

Does climbing one flight of stairs or walking one city block make you short of breath?			
Do you have congestive heart failure?			
Have you ever had angioedema?			
Have you ever had ischemic heart disease (including but NOT limited to acute myocardial infarction, a history of myocardial infarction and/or angina)?			
Have you ever had a heart attack, chest pain, angina or chest tightness?			
Have you ever had heart failure or fluid in your lungs?			
Do you have a heart murmur or valve problem?			
Have you ever been treated for an irregular heartbeat?			
Do you have uncontrolled hypertension?			
Have you ever had bleeding disorders?			
Have you ever had a history of ulcers?			
Do you have indigestion, heartburn, or a hiatus hernia?			
Have you ever had inflammatory bowel disease?			
Do you have liver disease or a history of jaundice or hepatitis?			
Do you have a kidney problem?			
Do you have hyperkalemia?			
Have you had epilepsy, blackouts, seizures or a stroke?			
Please read all questions carefully and respond by placing a check (✓) in the "YES", "NO" or "Do not know" box.			
Table 2. Exclusion criteria:	**Responses**		
	No	**Yes**	**Do not know**
Have you had problems with blood clots or excessive bleeding?			

Have you or any member of your family reacted to an anaesthetic or the placement of the breathing tube?			
Do you have diabetes?			
Do you take insulin?			
Do you have cancer?			
Is there any possibility you may be pregnant?			
Do you have sleep apnea?			
Medications			
Are you currently using of high-dose opioids (>60 mg equivalents of morphine), gabapentinoids, antidepressants, antipsychotics, or cannabinoids?			
Are you unable to receive an interscalene block?			
Do you have a contraindications to pregabalin, or both celecoxib and naproxen EC, or both ropivacaine and bupivacaine?			

Table 3. Assessment	**Responses**		
	No	**Yes**	**Do not know**
Do you have any other important medical problems?			
If yes, please list:			

Table 4. Medications	**Responses**		
	No	**Yes**	**Do not know**
Do you use any medication?			
If yes, please list:			

Should you choose to participate you will have a consultation with one of the physicians and a research assistant 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.