Comprehensive Research Experience for Medical Students
Summer Research Program 2019

Supervisor/Project Information Form

Due February 20 2019 by email to crems.programs@utoronto.ca

Supervisor Name: Dr. Nucelio Lemos

Project Title: The impact of gabapentin/baclofen suppositories on chronic pelvic pain – a pilot prospective cohort

Hospital/Research Institution: Mt. Sinai Hospital, University of Toronto Faculty of Medicine

Email: nucelio.lemos@utoronto.ca

Field of Research (2 keywords): chronic pelvic and perineal pain; pelvic floor dysfunction

Department: Department of Obstetrics and Gynecology, Mt. Sinai Hospital

School of Graduate Studies Appointment (IMS, LMP, IHPME etc)? Yes/No: NO If YES, please name:

Project Title: The impact of gabapentin/baclofen suppositories on chronic pelvic pain – a pilot prospective cohort

Brief Project Description (‹300 words):

Myofascial pelvic pain is a common cause of chronic pelvic pain that can be a debilitating. It may contribute to other conditions such as irritable bowel syndrome, endometriosis, and pudendal neuralgia. Many non-pharmacological and pharmacological treatments are used in management, however there is a lack of evidence demonstrating efficacy of the drugs used to treat myofascial pain.

A prospective observational study will be conducted on patients who have been prescribed compounded gabapentin/baclofen suppositories (rectal or vaginal) for myofascial pain at the Pelvic Functional Surgery Clinics of Mt. Sinai and Women's College Hospital. Data regarding pain and function prior to and after the use of the compounded suppository at each follow-up visit will be collected from the patient's charts and used to analyze the effect of the intervention on the named parameters. All data will be collected from the standard patient intake questionnaires, which are filled out by all patients in Dr. Lemos' clinics, both on the first consultation as well as in follow ups (1, 3, 6 months). Recruitment is expected to be completed in 6 months and complete the 6-month follow-up period for all subjects at one year from the beginning of the study.

The primary objective of this study is to assess the efficacy and safety of Baclofen/ Gabapentin compounded suppositories on pain relief, sexual function, and quality of life in patients with myofascial pelvic pain as measured using visual analog scale scores. We also want to determine the sample size that would allow for statistical power of 80% and significance threshold of 5% in a double blind, randomized placebo-controlled trial assessing the efficacy of baclofen/gabapentin suppositories.