Supervisor Information

Name: Christine Brezden-Masley

Email: brezdenc@smh.ca

Degree(s): MD, PhD, MSc

SGS Department: Oncology (Medical)

Academic Rank: Associate Professor

Field of Research: Oncology

Research Institution Affiliation (if applicable): St. Michael’s Hospital / Li Ka Shing Research Institute
Allocation of student contact time: 0.5 – 1.0 hour / week
(number of hours per week YOU are available to the student for any concerns
or to review progress)
Project Information (for posting on GDipHR website)
Title: Chemotherapy-induced fatty liver disease in colorectal cancer patients undergoing chemotherapy: Do statins play a role?
Description (max 500 words):
Liver is the main organ for metabolism, activation, catabolism and excretion of most drugs. Drug induced fatty liver has been described in the literature as part of non-alcoholic fatty liver disease (NAFLD).

Anecdotally, Medical Oncologists in the Medical Day Care Unit have observed that patients on various chemotherapy regimens for colorectal cancer develop NAFLD at a higher frequency than would normally be expected. In clinical practice, radiological examinations done for patients undergoing chemotherapy frequently describe development of fatty liver changes; however, little information is available on how frequently these changes are reported, and this observation is based on local clinical experience. It has also been observed that patients on statin therapy, a class of lipid-lowering medications, appear to develop NAFLD at a different rate than their counterparts not taking any statin therapy. After a thorough review of available literature, we have found that this topic has never been investigated.

At St. Michael’s Hospital (SMH), patients diagnosed with colorectal cancer receive CT scans of the chest, abdomen, and pelvis at baseline, prior to receiving any systemic therapy, in order to have a baseline evaluation of their disease. Following completion of therapy they receive CT scans every 6 months for 3 years, and then annually for another 5 years, to ensure no recurrence of disease.
The successful CREMS student will complete the following during their orientation period:

Retrospective data collection of approximately 300 colorectal cancer patients seen at St Michael’s Hospital over the last 10 years will be completed prior to the CREMS student start date. This retrospective study will allow us to describe the rates of NAFLD in patients treated for colorectal cancer as well as to compare whether patients on statins experience chemotherapy-induced fatty liver less frequently than their counterparts who are not on statins. The CREMS student will analyze the retrospective data set with the help of a St Michael’s statistician and will prepare this data for publication. Concurrently, they will begin designing a prospective clinical study.

The successful CREMS student will begin the following during their Summer I period, and through the remainder of their terms:

Develop a prospective clinical study looking at the use of statins as a protective medication for NAFLD for colorectal cancer patients undergoing chemotherapy. We want to evaluate whether patients that are on statins, a class of lipid-lowering medications, throughout chemotherapy develop NAFLD at a lower frequency than patients not on statins. The CREMS student will prepare the ethics submission, Health Canada submission, data collection forms, consent forms. These activities will be supported by the Hematology Oncology Clinical Research Group (co-directed by Dr. Brezden-Masley). The CREMS student will perform prospective data collection, data analysis and write up of study results.

If human subjects are involved, have the appropriate Research Ethics
Board approvals been obtained?

**X** Application Submitted – for retrospective component
Clinical trial to be designed and submitted by CREMS student.

Do you expect this work will be published within the 20 months?
**X** YES

**Student’s roles and responsibilities** (please be as specific as possible):

- Data analysis & Manuscript preparation (retrospective study)
- Clinical Trial Design, protocol development
- Support application process for trial funding opportunities
- Development of study related documents – consent forms, data collection forms, other patient facing materials
- Obtain regulatory approvals for trial conduct
- Patient recruitment, data collection, data analysis

*Please indicate who will serve as the student’s direct report for daily oversight (PI, PhD student, technician, etc...):* PI & Oncology Research Manager