



SAFETY

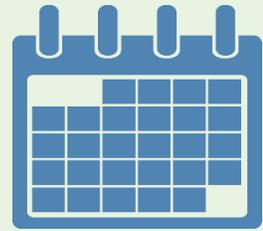
Surveillance After Extremity Tumor Surgery

October 2019 ■ Edition 1

Welcome! This is the first edition of the **Surveillance AFter Extremity Tumor surgery (SAFETY)** Trial Newsletter. This newsletter will provide an update on the progress of the study, as well as other important study information such as upcoming meetings or amendments to study documents!

STUDY RATIONALE AND IMPACT

Following treatment for a primary extremity soft-tissue sarcoma (STS), patients remain at risk for the development of local and systemic / distant disease recurrence. Metastasis (distant recurrence) to the lung is the most frequent single location of disease recurrence in STS patients, occurring in almost half of all patients. Therefore, careful post-operative surveillance is an integral element of patient care. However, the detection of metastases does not necessarily affect long-term survival and may negatively impact quality of life. Surveillance strategies have been identified as the top research priority in the extremity sarcoma field. The SAFETY trial will provide the necessary evidence to develop evidence-based surveillance guidelines and is poised to have a significant impact on post-operative care and outcomes of extremity STS patients.



STUDY OVERVIEW

The overarching objective of this trial is to answer the following research question:

Does the frequency and mode of surveillance affect patient survival following extremity STS surgery?

To do so, we will compare two surveillance frequencies (every 3 months vs. every 6 months) and two imaging modalities (chest CT scans vs. chest radiographs). Patients will be randomized to one of four treatment groups:

- Clinical assessment and **chest CT** scan every **3 months** for 2 years;
- Clinical assessment and **chest CT** scan every **6 months** for 2 years;
- Clinical assessment and **chest radiograph** every **3 months** for 2 years; or
- Clinical assessment and **chest radiograph** every **6 months** for 2 years.

Upon completion of the 2-year ‘intervention phase’, study participants will continue to be followed in the study every 6 months for another 3 years. The primary outcome is overall survival at 5 years post-randomization.

SITE INITIATION UPDATE

The following sites are actively working to complete the required study initiation activities before participant recruitment commences. Thank you for your support and perseverance!

Site	Country	Ethics Approval Status	Site Agreement Status	Site Training Status
Juravinski Hospital and Cancer Centre	Canada	Approved	In Progress	N / A
Mount Sinai Hospital	Canada	-	-	-
McGill University Medical Centre	Canada	-	-	-
Hôpital Maisonneuve-Rosemont	Canada	-	-	-
Holden Comprehensive Cancer Centre	USA	-	-	-
Oregon Health & Science University Hospital	USA	-	-	-
The Cleveland Clinic	USA	-	-	-
University of California Davis Medical Center	USA	-	-	-
Medical University Graz	Austria	-	-	-
Leiden University Medical Center	Netherlands	-	-	-
Hospital Vall d’Hebron	Spain	-	-	-

The recruitment target for the pilot phase of the SAFETY trial is **200** participants. To reach this target, the Methods Centre is actively seeking high volume sites with research support to join the pilot phase of the trial. If you know of any individuals who may be interested in participating in this collaborative study, please inform the **Methods Centre**.

SAVE THE DATES!

SAFETY PODIUM AT MSTS MEETING!

The SAFETY Protocol Development Study and the SAFETY Trial will be showcased as a podium presentation at the Musculoskeletal Tumor Society 2019 Annual Meeting in Portland, OR on **Thursday, October 3 at 8:05AM**.

The SAFETY Investigators have been listed as the author of this abstract. The details for your CVs are as follows:

Title: Surveillance After Extremity Tumor Surgery (SAFETY) Patient Survey: A Patient-Centered Approach to the Development of an International RCT

Authors: The SAFETY Investigators

Meeting: Musculoskeletal Tumor Society 2019 Annual Meeting

Date: Thursday, October 3, 2019

Time: 8:00 – 8:05AM

City: Portland, OR, USA



COLLABORATION DINNER IN PORTLAND!

To celebrate our ongoing collaborative research network, the SAFETY team will be hosting a dinner on **Wednesday, October 3 at Q Bar and Grill** in Portland, OR. We will be meeting at 7:45PM at the MSTs Welcome Reception and walking together to the restaurant. If you are interested in attending the dinner but have not yet RSVPed, please contact **Tricia** via email (schnep@mcmaster.ca) or cell (289-244-6087)!

We look forward to dining with you in Portland!



SUCCESS BULLETIN!

FINAL ETHICS APPROVAL

We are pleased to report that the Methods Centre has received final approval from the Hamilton Integrated Research Ethics Board for the SAFETY Trial.

FUNDING UPDATE

At present, we have received the following funding to conduct the Canadian pilot study:

- Hamilton Academic Health Sciences Organization (HAHSO) Innovation Fund; and
- Canadian Cancer Society Research Institute (CCSRI) Innovation Grant.

We have also applied for a Canadian Institutes of Health Research (CIHR) Operating Grant to support the international expansion of the pilot trial. We expect to hear the result of our application in early 2020.



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CLINICAL TRIAL REGISTRATION

The SAFETY trial has been registered on ClinicalTrials.gov (NCT03944798).

SAFETY PROTOCOL PUBLISHED!

The SAFETY trial protocol has published in *BMJ Open*. The full article can be accessed online at: <https://bmjopen.bmj.com/content/9/9/e029054.info>.



FIRST SAFETY PARTICIPANT IDENTIFIED!

The first potential SAFETY trial participant has been identified at the Juravinski Hospital and Cancer Centre. We will approach the patient to participate in the study in the coming weeks. We look forward to more sites opening to recruitment soon!

METHODS CENTRE CONTACTS

If you have questions about any aspect of the study, do not hesitate to contact:

Dr. Michelle Ghert, Principal Investigator

ghertm@mcmaster.ca

Tel: (905) 387-9495 ext. 64089

Tricia Schneider, Project Manager

schnep@mcmaster.ca

Mobile: (289) 244-6087

Victoria Giglio, Research Assistant

gigliovt@mcmaster.ca

Mobile: (905) 550-2962