SAFETY

Surveillance After Extremity Tumor Surgery

May 2020 ▪ Edition 3

Welcome to the third edition of the **S**urveillance **AF**ter **E**xtremity **T**umor surger**Y** (SAFETY) Trial Newsletter!

RECRUITMENT UPDATE

We are pleased to report that as of 06 May 2020, **8** participants have been enrolled in the SAFETY trial!

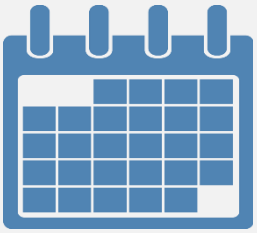
Site	Country	Enrolled Since Last Update	Enrolled to Date	Pilot Phase Enrolment Target
Juravinski Hospital and Cancer Centre	Canada	6	8	**10%**

SITE INITIATION UPDATE

Thank you to all the following sites that are actively working to complete the required study initiation activities before participant recruitment commences. Please do not hesitate to contact the Methods Centre for any assistance.

Site	Country	Ethics Approval Status	Site Agreement Status	Site Training Status
McGill University Medical Centre	Canada	In Progress	In Progress	N / A
Hôpital Maisonneuve-Rosemont	Canada	In Progress	In Progress	N / A
Hôpital Hôtel-Dieu	Canada	In Progress	In Progress	N / A
Huntsman Cancer Institute	USA	In Progress	In Progress	N / A
Hospital Universitario Austral	Argentina	In Progress	In Progress	N / A
Holden Comprehensive Cancer Centre	USA	In Progress	In Progress	N / A
University of Minnesota Medical Center	USA	In Progress	In Progress	N / A
Albany Medical Center	USA	In Progress	Finalized	N / A
Oregon Health & Science University Hospital	USA	In Progress	In Progress	N / A
Johns Hopkins Hospital	USA	In Progress	In Progress	N / A
Hospital Vall d'Hebron	Spain	In Progress	In Progress	N / A
University of Florida Health Shands Hospital	USA	In Progress	In Progress	N / A
Leiden University Medical Center	Netherlands	In Progress	In Progress	N / A
The Cleveland Clinic	USA	In Progress	In Progress	N / A
Hospital de Clinicas de Porto Alegre	Brazil	In Progress	In Progress	N / A
Medical University Graz	Austria	Provisional Approval	In Progress	N / A
University of California Davis Medical Center	USA	In Progress	In Progress	N / A
Yale New Haven Hospital	USA	In Progress	In Progress	N / A
Centro Traumatologico Ortopedico Hospital	Italy	In Progress	In Progress	N / A

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 + **Chest radiograph** Every **3 Months** for 2 Years	Clinical Assessment + **Chest radiograph** Every **6 Months** for 2 Years	Clinical Assessment + **Chest CT** Scan Every **3 Months** for 2 Years	Clinical Assessment + **Chest CT** Scan 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.

SUCCESS BULLETIN!

SAFETY WEBSITE

The SAFETY trial website is now live, which will serve as primary mode of communication for important information from the Methods Centre. If you are interested in becoming an investigator for the SAFETY Trial, please visit www.SAFETYrct.com to complete the **SAFETY Physician Trial Application** or to access the study documents.

SUCCESSFUL ENROLLMENT CONTINUES AT JURAVINSKI!

We are happy to report that McMaster University and the Hamilton Integrated Research Ethics Board have approved the continuation of the SAFETY trial at Juravinski Hospital and Cancer Centre throughout the COVID-19 pandemic. We continue to follow social distancing procedures by study personnel obtaining consent via telephone. We look forward to more sites opening to recruitment soon and will work together to ensure this trial is a success!

CLINICAL TRIAL REGISTRATION

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

TRICIA PREPARES FOR MATERNITY LEAVE!

We are excited to announce that effective the end of ***June 2020 until December 31st 2020, Tricia*** will be off on maternity leave! Although we will miss Tricia at the Methods Center during this time, we are excited for this new beginning for Tricia and her family!

During this time, **Victoria** will be your primary contact for study correspondence. In the coming months, please email both Tricia and Victoria with any study questions.

Congratulations Tricia!

The recruitment target for the pilot phase of the SAFETY trial is **80** 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.**

METHODS CENTRE CONTACTS

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

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