



Proximal Femur Reconstruction or Internal Fixation for Metastases

December 2024 | Edition 2

UPDATES

Welcome to the second edition of the *PERFORM Randomized Controlled Trial* newsletter! The overall objective of the *PERFORM* trial is to determine the effect of resection and reconstruction on patient-important outcomes compared to internal fixation for the stabilization of an impending or realized pathologic fracture in patients with metastatic bone disease (MBD) of the proximal femur. In this edition, we are excited to provide an update on study initiation including our **Provisional Ethics Approval**!

INVESTIGATOR MEETINGS

MSTS 2024 | Chicago | September 11, 2024: Dr. Michelle Ghert and her research team, Olivia Virag, Hadia Farrukh and Abbey Kunzli, attended the Musculoskeletal Tumor Society's Annual Meeting in Chicago, Illinois. Dr. Ghert and other investigators presented studies related to the *PARITY*, *SAFETY* and *PERFORM* Trials. While in Chicago, the team also held an **Investigator Meeting** for the *PERFORM* trial. This hybrid meeting was attended by **45 international investigators**. Elements of the *PERFORM* trial protocol were presented and discussed, and attendees participated in a discrete choice experiment to determine the hierarchy of the composite outcome as part of the trial's protocol development. The meeting minutes have been distributed and are available upon request.



PRIMARY OUTCOME: HEIRARCHAL COMPOSITE OUTCOME AND TRIAL SAMPLE SIZE

Our team has been working on the use of behavioral economic techniques to identify patient preferences for outcomes. To achieve this, we have virtually conducted a **discrete choice experiment** as part of our stakeholder engagement framework to quantify the outcome priorities of the target population. This process involved individual stakeholders being presented with hypothetical comparisons of different outcomes after surgical management of MBD of the proximal femur, such as a minimum clinically important difference in a patient-reported outcome measure (PROM), disease relapse requiring re-operation, re-operations for other indications, days at home, or mortality. By pooling responses from our sample of 86 stakeholders in this planning step, we have determined the relative importance of the outcomes that patients, surgeons and caregivers desire that would allow them to choose the more invasive surgery. **The final hierarchal composite outcome is outlined below.** The data in the table below has been extrapolated from the literature and has been used to determine the sample size of **318** participants.

Level	Outcome	Expected Outcomes		
		Overall	Internal Fixation	Resection and Reconstruction
1	Mortality at 12 months	30%	30%	30%
2	PROMIS Global Physical Function (patient-reported outcome measure) * at 4 months	3.5	4.0	3.0
3	Days at Home ** at 12 months	320	300	340

* Higher values = better function, minimal clinically important difference is 0.5. 'To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries or moving a chair?' (Range 5: completely to, 1: not at all).

** Days with no interaction with the healthcare system, patient diary reported.

NEXT STEPS: RESEARCH ETHICS AND SITE INITIATION

Our team is working closely with the Hamilton Integrated Research Ethics Board and Clinical Trials Ontario to have the application for research ethics for the PERFORM trial approved. This application will involve McMaster University's Surgery Methods Centre as the sponsor of the PERFORM Trial. **We are excited to announce that as of December 10th, 2024, we have received provisional approval!** Once we receive final approval, we will open the Physician Trial Application on the trial website to begin the study site selection process. The link will be shared at that time.

HIGHLIGHTS

NEW LOGO

Based on the discussion at the Investigator Meeting in Chicago, it was decided that arthroplasty would be included in the 'reconstruction' arm and therefore, the logo has been updated to 'Proximal FEmur **Reconstruction** or Internal Fixation fOR Metastases' from 'Proximal FEmur **Resection** or Internal Fixation fOR Metastases.'

GRANTS

[Canadian Cancer Society Breakthrough Grant](#): Thank you to our team of investigators, collaborators and knowledge users in preparing this grant application, which was submitted in October 2024. Once the award decision is announced, we will share any news with the team. Best of luck to everyone involved!

SURGERY METHODS CENTRE CONTACTS

If you have questions about any aspect of the PERFORM trial, please contact us:

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