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Biomarker-Driven, breast cancer treatment optimization of HER2 Targeted Therapy in Tanzania

The primary aim of this study is to analyze whether serum human epidermal growth factor receptor 2 (sHER2) can serve as a guiding biomarker for initiation and continuation of HER2 targeted therapy. Endpoint will be progression-free survival (PFS) assessed by RECIST 1.1 in all three treatment arms in subjects with metastatic sHER2-positive (sHER2+) treatment-naïve, breast cancer. In consideration of increased toxicities of multiple-agent therapy and high financial costs associated with it, there is growing interest in defining patient population where de-escalation therapy could be appropriate. We posit that by measurement of sHER2 we can guide discontinuation of trastuzumab without compromising efficacy of maintenance therapy and thus spare toxicity of trastuzumab therapy and decrease financial costs. This study is a multi-center, prospective biomarker study involving the major established cancer centers in Tanzania. Patients with metastatic treatment-naïve breast cancer with elevated sHER2 will be first treated with 6 cycles of docetaxel + trastuzumab. Serum Her2 will be tested within 6 days prior to Day 1 of each of the 6 cycles of therapy. After completion of 6 cycles, patients will be assigned or randomized to one of three treatment arms depending on sHER2 levels after chemotherapy induction. If sHER 2 levels remain unchanged or are elevated compared to their sHER2 level before treatment, then patient will be assigned to Arm 1. If their sHER2 level is decreased by at least 20% compared to baseline sHER2 level before treatment, then subjects will be randomly assigned to Arm 2 or to Arm 3. Serum HER2 will continue to be tested within 7 days prior to Day 1 of each of the remaining cycles of therapy. PFS will be assessed by RECIST 1.1 in each arm. This study will seek to establish a normal range and upper limit of normal value for sHER2 in healthy Tanzanian women of color seeking for cervical cancer screening at KCMC, estimate cost of care in all 3 treatment arms in subjects with metastatic sHER2+, treatment-naïve, breast cancer. Correlate sHER2+ with HER2 cell surface 3+ expression by IHC in tumor tissue.

Research Task 3.3

Supervisors
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