

Study Title:
Community Hospital Identification of High CV Risk Patients during Cancer Treatment (CHI)

ClinicalTrials.gov: [Community Hospital Identification of High CV Risk Patients During Cancer Treatment](#)

For Clinical Research Sites interested in participating in this study, please contact Robin Rosdhal by e-mail (rosdhal@wakehealth.edu) or by phone (336.713.6519).

PURPOSE:

The overall of this proposal is to test in community hospitals the utility of a 10-min magnetic resonance imaging (MRI) scan protocol combined with proprietary image analysis algorithms for detecting early cardiovascular (CV) injury during receipt of chemotherapy for breast cancer (BrC) and lymphoma. This technology provides health-care delivery systems with a time-efficient method to identify those at risk of a future CV event so that prevention can be implemented to prolong survival and reduce morbidity in cancer survivors.

Study Type:

Interventional

Study Design:

- *Intervention Model:* Single Group Assignment
- *Masking:* Open Label

Estimated Enrollment:

30

Study Start Date:

October 2015

Estimated Study Completion Date:

October 2017

Estimated Primary Completion Date:

April 2017 (Final data collection date for primary outcome measure)

Primary Outcome Measures:

- Change is being assessed of deteriorations in LVEF:
 - To determine if baseline to 2-month measures of left ventricular (LV) volumes, T1/T2 times, and/or aortic pulse wave velocity (all acquired within 10 minutes) can predict baseline to 6-month post chemotherapy deteriorations in LVEF, as measured by a typical 45-min MRI.
 - *Time Frame:* Baseline to 2 Months
 - *Designated as safety issue:* No

Secondary Outcome Measures:

- Change is being assessed of deteriorations in LVEF at 6 months:
 - To compare the Albus 10-min MRI metrics with both ECHO (including PWV) and cardiac serum biomarkers (TnI) for predicting baseline to 6 month deteriorations in LVEF.
 - *Time Frame:* Baseline to 6 Months
 - *Designated as safety issue:* No
- Change is being assessed of deteriorations of CV function:
 - To use exploratory algorithmic modeling to obtain optimal strategies for determining the combination of metrics (10-min MR, ECHO, serum biomarkers) at 2-months that predict the 6-month post chemotherapy deteriorations in CV function.
 - *Time Frame:* 2 Months

➤ *Designated as safety issue: No*

Detailed Description:

While recent research indicates that conventional MRI, advanced echocardiography (global longitudinal strain and 3D) and serum biomarkers can detect CV injury early after receipt of Chemotherapy, these methods require lengthy and difficult examinations that are not routinely executed in community hospitals where the majority of patients with BrC & lymphoma are treated. Yet, 1-month deteriorations in traditional 45-min MRI measures are known to forecast 6-month subclinical deteriorations in left ventricular ejection fraction (LVEF) that are associated with CV events. At the same time, new observational data indicate therapy with HMG-CoA reductase inhibitors/statins administered early during receipt of Chemotherapy may prevent subsequent cardiac dysfunction and CV events. Our MRI fast scanning techniques remedy these community hospital implementation obstacles.

In this proposal, the investigators propose to test the utility of these fast scans within an existing funded randomized clinical trial R01HL118740 of generic atorvastatin that is researching methods to prevent cardiotoxicity in patients treated with Chemotherapy for BrC and lymphoma (taking advantage of significant existing clinical trial resources). This study allows us to address our over-arching goal: to determine the optimal implementation (alone or in combination with other tests) of our proprietary MRI processes for forecasting CV injury in patients treated with Chemotherapy in community hospitals through performance of a Phase II comparative effectiveness study within an ongoing clinical trial.

****For more information, please follow the [ClinicalTrials.gov](#) link provided at the top of page 1****