

Study Title:
Improving Resection Rates among African Americans with Non-small Cell Lung Cancer (NSCLC)

ClinicalTrials.gov: [Improving Resection Rates Among African Americans With NSCLC](#)

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:

This is a randomized, interventional trial in which the navigation is the intervention. Phase is not applicable. The study is a randomized trial to evaluate the impact of a nurse-led patient navigation intervention in improving rates of receipt of lung-directed therapy with curative intent (LDTCI) among African Americans with early stage lung cancer. Study sites are cluster-randomized to either the usual care study arm or the to the navigation intervention study arm. Randomization occurred at the level of the study site rather than at the level of individual participants. There are two arms: Usual Care arm and Intervention arm.

Study Type:

Interventional

Study Design:

- *Allocation:* Randomized
- *Endpoint Classification:* Efficacy Study
- *Intervention Model:* Parallel Assignment
- *Masking:* Open Label
- *Primary Purpose:* Treatment

Estimated Enrollment: 200
Study Start Date: January 2015
Estimated Study Completion Date: November 2017
Estimated Primary Completion Date: November 2016 (Final data collection date for primary outcome measure)

Primary Outcome Measures:

- Receipt of lung-directed therapy with curative intent (LDTCI):
 - Confirmed by medical record review
 - Inquiry at time to follow-up survey
 - *Time Frame:* 12 Months Post-Enrollment
 - *Designated as safety issue:* No

Secondary Outcome Measures:

- Receipt of surgical and/or radiation oncology consultation:
 - Defined as outpatient or inpatient consultation with a general or cardiothoracic surgeon and/or radiation oncologist to discuss LDTCI for NSCLC within 4 months post-diagnosis of probable/proven early stage NSCLC.
 - Confirmed by medical record review
 - *Time Frame:* Baseline, 3, 6, 9, and 12 months post-enrollment
 - *Designated as safety issue:* No

- Time to LDTCI for patients who received LDTCI only:
 - Confirmed by Medical Record Review
 - Inquiry at time of follow-up survey
 - *Time Frame*: Baseline, 3, 6, 9, and 12 Months Post-Enrollment
 - *Designated as safety issue*: No
- Satisfaction with Care Received, Patient Satisfaction:
 - *Time Frame*: 6 months post-enrollment
 - *Designated as safety issue*: No
- Time of Death:
 - Inquiry at time of follow-up survey
 - Confirmed by Medical Record Review
 - Inquiry of cancer registries at study sites
 - Inquiry of Social Security Death Index
 - *Time Frame*: Baseline, 3, 6, 9, and 12 Months Post-Enrollment
 - *Designated as safety issue*: No

Detailed Description:

The burden to participants will be minimized to enhance retention. Patients in the usual care arm receive the current "gold standard" of treatment. The patients in the intervention arm are assigned to a PN, who helps to reduce the barriers to care that could negatively impact the patients' receipt of LDTCI. The telephone-administered survey is administered to all study participants at baseline and at 3-, 6-, and 12-months post-enrollment. It takes approximately 30-40 minutes to administer. The telephone mode of survey administration was chosen to reduce the number of visits that would be required by each patient. Interviews are scheduled at the convenience of the study participants. To further reduce burden to the study participants, the interviewers offer breaks during the interview process. Patients in both arms undergo standard therapy visits. Patients in the navigation arm receive standard therapy visits plus the navigation intervention. Outside of the standard therapy visits, no additional clinic visits are required of the study participants.

Once informed consent has been obtained and the informed consent document is received, the SSC/PN will communicate to the MUSC HCC study staff the participant's contact information and that the participant is ready for baseline survey administration. All the study surveys will be administered by trained MUSC HCC study staff via telephone. A survey answer guide will be provided to the participant either in-person or via mail prior to administration of the baseline survey.

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