Protocol Title: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Target Population: Lung Carcinoma

Summary: This randomized phase III trial studies how well management of a tobacco treatment intervention works in reducing surgical complications in patients with newly diagnosed lung cancer who smoke cigarettes.

Key Inclusion Criteria:
- Eligible patients will have a new diagnosis of Lung Cancer and have sought a surgical consult relating to this diagnosis.
- Surgery must be scheduled no sooner than 10 Days after randomization and no more than 12 Weeks after randomization.
- Have smoked daily or nearly every day in the previous 6 Months up to the date of surgical consult AND have smoked at least one puff in the previous 7 Days.
- Motivated to stop smoking, as indicated by a score of 6 or above on the Contemplation Ladder.
- Within the 30 Days before registration, no use of:
  - Pharmacologic treatment for smoking cessation, including Bupropion or nicotine replacement therapy
  - Any nicotine delivery system (i.e., e-cigarettes and vape products)
  - Be enrolled in any formal behavioral treatment program for tobacco dependence
- No allergies to and not currently using Varenicline.
- No suicidal thoughts as indicated by a positive (1+) response to the PHQ9.
- No active untreated clinically significant psychiatric condition (psychosis, bipolar disorder, or depression).
- Negative pregnancy test done ≤ 7 Days prior to registration, for women of childbearing potential only.
- No unstable angina, myocardial infarction, or coronary angioplasty within the past 3 Months or an untreated cardiac dysrhythmia.
- No history of seizures.
- No unstable neurologic, hepatic, renal, cardiovascular, lymphatic, or metabolic disease.
- Not currently on renal dialysis or has a history of significant renal impairment.
- No recent history (≤ 90 Days) of substance abuse (outside of tobacco) defined by National Institute on Alcohol Abuse and Alcoholism (NIAAA) as:
  - If male, drinking > 14 alcoholic beverages per week for past 1 Month
  - If female, drinking > 7 alcoholic beverages per week for past 1 Month
  - Use of cocaine, heroin, club drugs (i.e., 3,4-methylenedioxyamphetamine (MDMA)/"ecstasy"), methamphetamine, or hallucinogens (e.g., lysergic acid diethylamide [LSD]) at any time during the past 1 Month
  - Use of marijuana on a weekly basis for the past 1 Month
- No other household member or relative participating in the study.
- No known history of any condition or factor judged by the investigator to preclude participation in the study or which might hinder study adherence.
- Calculated Creatinine Clearance (CrCl) ≥ 30 mL/min.
  - For females, use 85% of CrCl value.

Contacts:
- Principal Investigator: Brian Pettiford, MD
- Research Nurses (RN): Nicole Duffaut (nicole.duffaut@ochsner.org, ext. 23683)
  Melanie Breaux (mibreaux@ochsner.org, ext. 24478)

For additional information: https://clinicaltrials.gov/ct2/show/NCT02856581