Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team

Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Rationale

Can surgical teams capitalize on a teachable moment regarding the harmful effects of smoking that will reduce surgical complications among lung cancer patients who smoke? In this study, newly diagnosed lung cancer patients who smoke and are expected to undergo surgery will receive a brief no-smoking message from the surgical team and behavioral support provided by NCI's telephone smoking quitline (1-877-44U-QUIT). In addition, patients will be randomized to receive either varenicline or placebo. By helping smoking surgical patients stop smoking, we hope to reduce post-operative complications through 24 weeks following surgery, improve the patient's quality of life, reduce post-operative care, and reduce smoking in lung cancer patients.

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team
Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Specific Aims

Primary

- To determine if varenicline, when added to a behavioral intervention consisting of a brief clinician-delivered intervention with tobacco quitline follow-up, **decreases postsurgical complications through 24 weeks after surgery in lung cancer patients who undergo surgery** and are motivated to stop smoking.

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

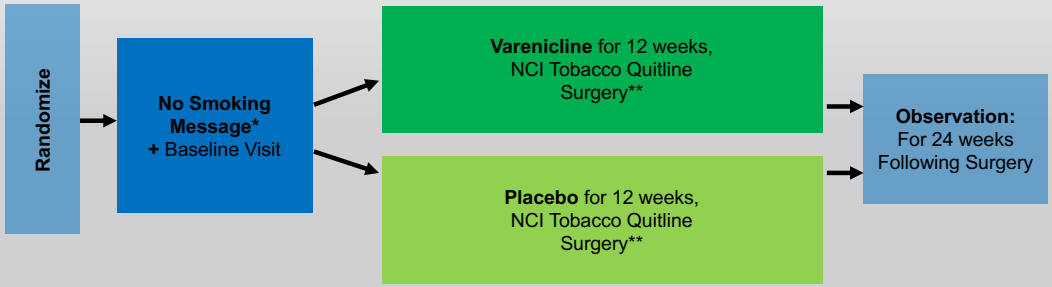
Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team

Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Study Schema



* + The No-Smoking Message must be delivered **after** randomization

** Surgery must occur after the target quit date (TQD) defined at baseline and can be performed no sooner than 10 days after randomization and no more than 12 weeks after randomization.

783 invited to study – 626 expected to undergo surgery

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team
Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Visit Flow Clarifications

It is understood that clinical practices may vary with respect to how patients eligible for this study are identified and treated.

Screening: It is expected that at the time patients are referred to the surgical clinic (e.g., from pulmonary or interventional radiology service, primary care physicians), they will be screened for this study. Alternatively, site staff may review internal medical records to identify patients eligible for the study who have not yet completed the surgical consult. Time permitting, pre-registration tests, observations, and questionnaires may be completed on the same day as registration/randomization and the Baseline Visit.

Registration/Randomization: Patients must be registered/randomized following informed consent and prior to the Baseline Visit.

Baseline Visit: The Baseline Visit will include the delivery of the No-Smoking Message by a surgical team member, collection of saliva for cotinine measurement, baseline assessments, and the completion of the baseline questionnaires.

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team

Mayo Clinic

TAP TO RETURN TO KIOSK MENU

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

Please use the headings above to navigate through the different sections of the poster

Study Calendar

	Consent/ screen†	Baseline*	Day of Surgery**	Week 6***	Week 12***	Week 18***	Week 24***
Visit Type	In person	In person	In person	In person	Phone/in person	Phone/In person	In person
Med Hx/PE	X	X					
Screen/registration	X						
AE/Con Meds		X**	X**	X**	X**	X**	X**
Quit Message		X					
Quitline		X					
Study Med		X	X	X			
PHQ-9		X		X	X		X
Tobacco Use Assessment		X	X	X	X	X	X
SEQ-12		X		X	X		X
LASA		X	X	X	X		X
Saliva		X	X	X	X	X	X*
Blood		X					

† Pre-study testing may be performed on the same day as the baseline visit (see also Section 7.1).
- Baseline: After randomization and at the time the surgical message is discussed with the cancer patient. If performed within 7 days prior to baseline, H & P and Tobacco Use Assessment need not be repeated.

** Surgery must occur after the TQD defined at baseline and can be performed no sooner than 10 days after randomization and no more than twelve weeks after randomization.
*** Post surgery visits can be +/- 14 days

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team

Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Surgical Adverse Events – Primary Endpoint

- 30-day mortality
- 30-day re-hospitalization
- 1-year mortality
- Anastomotic failure
- Anesthesia-related respiratory complications
- Bleeding (transfusions > 5 U)
- Coma (> 24 hours)
- Deep venous thrombosis/ thrombophlebitis
- Failure to wean from the ventilator
- ICU readmission
- Impaired bone healing
- Implant loss (breast reconstruction)
- Increased postoperative pain
- Renal insufficiency/failure
- Return to operating room
- Sepsis/septic shock
- Stroke/cerebral accident
- Surgical infection (organ space)
- Surgical site infections
- Urinary tract infections
- Increased postoperative surgical stay
- Increased scarring and asymmetry
- Intubation (unplanned)/re-intubation
- Lower rates of successful digital replantation (microsurgery)
- Myocardial infarction
- Pneumonia
- Prolonged intubation
- Prolonged ventilator support
- Pulmonary complications
- Pulmonary embolism
- Reduced skin flap survival
- Vascular complications
- Vein graft failure
- Venous thromboembolism
- Ventilator (> 48 hours)
- Wound healing (delayed)
- Wound infection (sternal)
- Wound infections (superficial and deep)

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team
Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Surgical Training and Credentialing Requirements

- The surgeon does not have to be the local "PI" of the study, but s/he does need to be a registered NCI investigator, as s/he will be the person to deliver the no-smoking message and assess the surgical complications.
- There are online training modules for surgeons and staff.
- Training must be confirmed by the Study Chair prior to enrolling patients.

Alliance A211401: Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients Who Smoke Cigarettes

Ivana T. Croghan, PhD and Jeff Sloan, PhD on behalf of the A211401 study team

Mayo Clinic

TAP TO RETURN TO KIOSK MENU

Please use the headings above to navigate through the different sections of the poster

Funding Support

Alliance A211401 is funded by the National Institutes of Health through National Cancer Institute grant awards, and in part by Pfizer, Inc.

Contact Us

Study Chair: Ivana T. Croghan, PhD
E-mail: croghan.ivana@mayo.edu
Phone: 800-848-7853

Protocol Coordinator: Rachel E. Wills
E-mail: rwills@uchicago.edu
Phone: 773-702-9814