Lung Cancer and Thoracic Oncology Studies

Screening and Epidemiology Studies

**CT Scan Lung screening**

Screening for Lung cancer in Higher risk but asymptomatic smokers by using Low-Dose non-contrast CT scans of the chest. Patients age 50 or older with more than 10 pack years of smoking are eligible to enter. Screening is free for appropriate candidates. Follow-up recommendations will be forwarded to referring physician.

This study will continue to evaluate the subsets of patients at higher risk for lung cancer and the role that CT scan screening plays in reducing mortality from lung cancer. Results will be coordinated with the IELCAP group (International Early Lung Cancer Action Project)

**SWOG 0424: Molecular Epidemiology of Lung Cancer**

A questionnaire that is administered to non-smoking Men and women to try to identify rationale for gender differences in incidence and severity of lung cancer. Study is open to recently diagnosed non-smoking men and women with stage I, II or III disease. Smoking arm of trial has reached accrual goals.

The postulate is that hormonal influences may account for some of the observed increased incidence of lung cancer in non-smoking women as opposed to men and the apparent higher incidence of lung cancer in women who smoke but have a relatively lower dose of smoke exposure

Adjuvant Studies

**MAGRIT study:** A double-blind randomized, placebo-controlled Phase III study to assess the efficacy of MAGE vaccine antigen-specific cancer immunotherapy as adjuvant therapy in patients with resectable MAGE-A3 positive non small cell lung cancer.

The study will evaluate the potential role and efficacy of a lung cancer vaccine (cancer immunotherapy) for patients who have had their tumors completely removed. Patients will be randomized in a 2:1 fashion to vaccine therapy vs. placebo to assess if immunotherapy can prolong patient’s lives after removal of their tumor. Patients may be enrolled up to 12 weeks after surgery
Locally advanced studies (stage IIIA and IIIB)

**START study:** *Stimulating Targeted Antigenic Responses To NSCLC. A multicenter randomized, phase III study of the cancer vaccine Stimuvax (L-BLP 25) in non small cell lung cancer subjects with unresectable stage III disease*

The study will investigate the efficacy of a tumor vaccine, Stimuvax, in patient with unresectable locally advanced lung cancer. Patient’s may been enrolled up to 12 weeks after chemotherapy with radiation is complete.

**EVANS 169: Correlation Of Pathology And FLT-PET Post Induction Therapy**

This study is open to Stage IIIA patients who are undergoing planned induction therapy with chemotherapy and radiation prior to restaging and surgical resection. A novel radionucleide agent FLT (fluoridated thymidine) is used as the marker in the post treatment PET scan to try to distinguish viable dividing residual tumor in the treated area. It is postulated that since this scan is actually looking at a marker of nucleotide synthesis it may be more accurate than the standard FDG PET scan that utilizes a radiolabeled sugar molecule to determine biologic activity.

**RTOG 0617 Comparison of standard dose RT (60 GY) versus high dose 74 Gyconformal RT with concurrent and consolidated Carbo/Paclitaxel+-Cetuximab in Unresectable patients with Stage IIIA & IIIB disease with no distant metastasis**

Local -Regional Disease Studies in High Risk patients

**EVANS 171 Sublobar Lung Resection and Intraoperative Permanent Interstitial Brachytherapy**

A study of high risk Stage I Non small Cell Lung cancer patients who are deemed unable to tolerate standard lobectomy. A limited resection of the lung is performed and Intraoperative I-125 Brachytherapy seeds are sewn into the margins of resection sometimes with DaVinci Robotic assistance in an attempt to reduce the risk for local recurrence. It is known that resections less than lobectomy have a high risk for local recurrence, initial evidence suggests that brachytherapy implants can reduce that risk.

**RTOG 0813: Stereotactic Lung Radiosurgery in Medically Inoperable Early Stage Non Small Cell Lung cancer patients**

T1-2, N0, M0, tumor size <5cm, potentially gross resection with negative margin, Exclusion: prior RT, prior Chemotherpy, plans for pt to receive Chemo, standard fractioned RT &/or surgery.
Frontline Metastatic Studies (stage IV) – Patients with stage IV lung cancer that have yet to receive any chemotherapy

**H3E-US-S130 study**: A multicenter phase III randomized study of pemetrexed + carboplatin followed by pemetrexed versus carboplatin + paclitaxel + bevacizumab followed by bevacizumab

The study is evaluating two different maintenance chemotherapy schedules for patients with stage IV lung cancer. Maintenance chemotherapy (continuing chemotherapy indefinitely) has become a standard of care for patients with stage IV lung cancer.

**IMCL CP13-0811**: A randomized, open-label, stratified phase 2 trial of gemcitabine, carboplatin and cetuximab with or without IMC-AI2 (Cixutumumab) in patients with advanced/metastatic non small cell lung cancer

The study is evaluating testing a drug therapy, Cixutumumab, an insulin like growth factor antibody in patients with stage IV lung cancer. Recently it has been discovered that insulin-glucose pathways may cause cancer growth in lung cancer. This antibody potentially blocks this pathway.

Second line metastatic studies (stage IV) – Patients with stage IV lung cancer receiving a second line drug

**14T-MC-JVBP**: A phase 3 randomized, double blinded study of docetaxel and ramucirumab versus docetaxel and placebo in the treatment of stage IV non-small cell lung cancer following disease progression after one prior platinum –based therapy

This study will evaluate a new angiogenesis inhibitor, ramucirumab, in combination with standard, second line chemotherapy. Angiogenesis is thought to play a critical role in lung cancer growth, proliferation and survival. This antibody has been proven to block this pathway.

**PX-866**: A phase I/II study of PX-866, a PI-3kinase inhibitor, in combination with docetaxel in patients with stage IV squamous cell cancer of the head and neck and lung. This study will evaluate the potential role of blocking the PI-3K pathway which is thought to play a critical role in the tumor (squamous cell, specifically) growth and proliferation.
OTHER TRIALS

**ILHCP**  Surgical Cytoreduction +Intraoperative Intrathoracic Hyperthermic Chemotherapy (Cisplatin) Perfusion for Advanced Pleural Malignancies

This study evaluates the use of heated intrapleural chemotherapy perfused in the chest after resection of all gross disease from pleural metastasis The concept is to treat residual microscopic disease with highly concentrated chemotherapy in the pleural space while avoiding systemic toxicity.

Main disease to be treated would be thymic malignancies, pseudomyxoma, metastases from extrathoracic disease, mesothelioma and highly selected lung cancer patients.

**09-206 Outcome following robotic thymectomy - for myasthenia gravis: a prospective trial in patient with or without thymoma**

This trial is evaluating the peri-operative parameters and long term outcomes (symptom control and thymoma recurrence) in patients who undergo Da Vinci Robotic assisted thymectomy compared to a cohort of similar stratified patients who have undergone thymectomy via sternotomy

**09-113 Tumor, perioperative Blood Sample and clinical data banking for cancer, physiology immunology and other research studies**

For information on how to refer a patient to one of these studies please contact Continuum Cancer Centers of New York Comprehensive Thoracic Oncology Program 212 636-3333