

FAST FACTS

A082402: INVOLVED-STATION, INTENSITY-MODULATED POST-OPERATIVE RADIATION THERAPY (I²-PORT) FOR RESECTED NON-SMALL CELL LUNG CANCER WITH RESIDUAL MEDIASTINAL ADENOPATHY AFTER NEOADJUVANT THERAPY (YPN2)

Eligibility Criteria

3.2.1 Documentation of Disease:

- ___ Histopathologic diagnosis of NSCLC, may have mixed or multiple histologies but no small cell component.
- ___ No known EGFR mutation or ALK rearrangement.
- ___ No metastatic disease (M0) per most recent PET/CT and head CT/MRI imaging.
- ___ No disease progression per CT chest (including upper abdomen as per standard practice) with IV contrast (unless IV contrast is contraindicated) or FDG-PET performed post-neoadjuvant therapy ≤ 90 days prior to registration, either before or after surgery.
- ___ No metastatic disease (M0) per head CT/MRI imaging.

3.2.2 Prior Treatment/Surgery:

- ___ Prior treatment with 2–4 cycles of neoadjuvant systemic therapy with any guideline (NCCN) concordant regimen.
- ___ Lobectomy or greater oncologic surgical resection within 8 weeks prior to registration.
- ___ Complete (R0) resection showing ypN2 disease.
- ___ No prior radiotherapy to the lungs or mediastinum.
- ___ No treatment with a VEGF inhibitor ≤ 90 days prior to registration or plan to treat with adjuvant systemic therapy including a VEGF inhibitor.

3.2.3 Age ≥ 18 years

3.2.4 ECOG Performance Status ≤ 2

3.2.5 Required Initial Laboratory Values:

Absolute Neutrophil Count (ANC)	$\geq 1,000/\text{mm}^3$
Platelet Count	$\geq 50,000/\text{mm}^3$
Calc. Creatinine Clearance	$\geq 30 \text{ mL/min}$
Total Bilirubin	$\leq 3 \times$ upper limit of normal (ULN)
AST (SGOT)/ALT (SGPT)	$\leq 5 \times$ upper limit of normal (ULN)

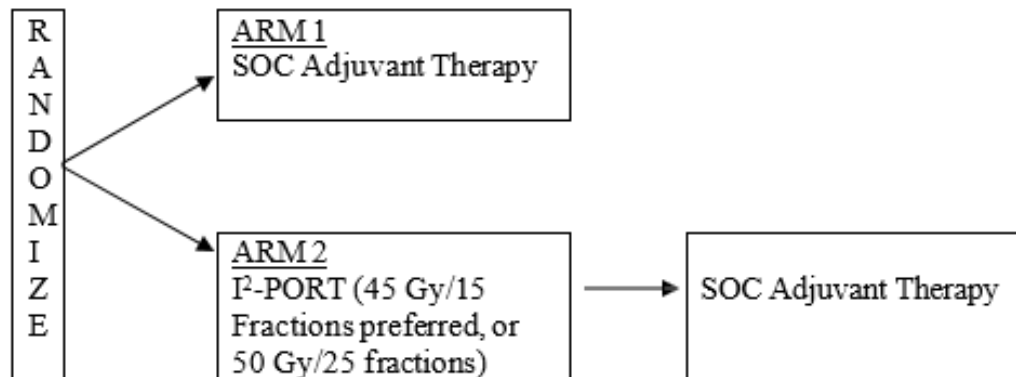
3.2.6 Not pregnant, because this study involves radiation therapy, which has known genotoxic, mutagenic and teratogenic effects. Therefore, for women of childbearing potential only, a negative urine or serum pregnancy test done ≤ 7 days prior to registration is required.

3.2.7 Comorbid Conditions

- **Patients with a prior or concurrent malignancy** whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.
- **Cardiac function:** Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better.
- **No idiopathic pulmonary fibrosis requiring anti-fibrotic medication:** Patients with idiopathic pulmonary fibrosis or inflammatory/interstitial lung disease compromising pulmonary function or requiring ongoing treatment with nintedanib, pirfenidone, or other anti-fibrotic drug are excluded.

3.2.8 HIV-infected patients on effective anti-retroviral therapy with an undetectable viral load within 6 months are eligible for this trial.

Schema



Stratification Factors

Patients will be stratified according to the following factors prior to randomization:

1. Single-station (N2a) vs. multi-station (N2b) nodal disease per AJCC 9th edition
2. Adequate vs. inadequate regional nodal sampling
Adequate sampling is defined as surgical assessment of at least one hilar (N1) and at least three mediastinal (N2) nodal stations