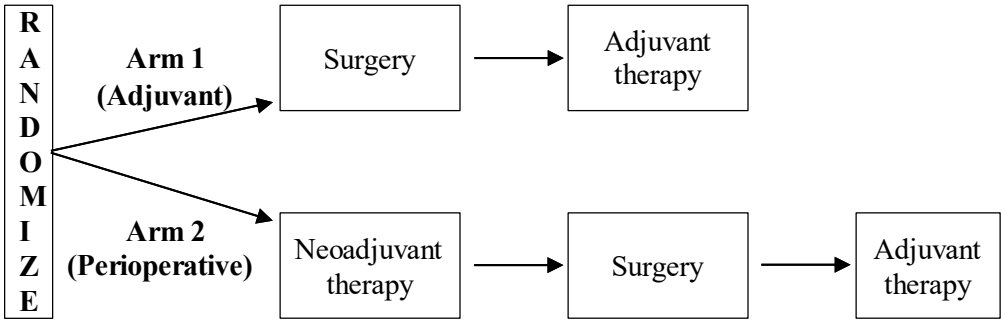
PERIOPERATIVE VERSUS ADJUVANT SYSTEMIC THERAPY IN PATIENTS WITH RESECTABLE NON-SMALL CELL LUNG CANCER – PROSPECT LUNG

Eligibility Criteria

- Histologic or cytologic confirmation of surgically resectable stage IIA to IIIB NSCLC (per AJCC 9th edition) or stage IIA to IIIB NSCLC (per AJCC 8th edition) up to single station N2
- Age ≥ 18 years
- ECOG PS ≤ 2 (or Karnofsky ≥ 60%)
- No prior treatment for NSCLC or administration within 5 years
- No previous malignancy within 3 years

Schema



Patients will be followed for 10 years or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

Adjuvant radiation therapy is allowed during protocol therapy in patients with positive surgical margins.

3.0 On-study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient: for example, medical conditions such as uncontrolled infection, uncontrolled diabetes mellitus or cardiac disease which, in the opinion of the treating physician, would make this protocol unreasonably hazardous for the patient. Early multidisciplinary evaluation of patients by surgeons and medical oncologists is encouraged. Clinicians should use their clinical judgement and have discussions with potential trial participants to assess their ability to follow protocol requirements safely.

Women and men of reproductive potential should agree to use an appropriate method of birth control throughout their participation in this study due to the teratogenic potential of the therapy utilized in this trial. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives or double barrier method (diaphragm plus condom).

3.1 Eligibility Criteria

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following page(s). Please note that an optional signature line has been provided for use by institutions wishing to use the eligibility checklist as source documentation.

When calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test were done on a Monday, the Monday one week later would be considered Day 7.

___ **3.2.1 Documentation of Disease**

___ **Histologic Documentation:** Histologically or cytologically confirmed surgically resectable stage IIA to IIIB NSCLC according to the AJCC 9th edition (stage IIA to IIIB NSCLC up to single station N2, according to the AJCC 8th edition).[14]

Note: Patients with resectable stage N2a or T4 are eligible, but patients with stage N2b or N3 are not eligible. Patients with known EGFR or ALK alterations are excluded.

___ **3.2.2 Age ≥ 18 years**

___ **3.2.3 ECOG Performance Status ≤ 2 (or Karnofsky ≥ 60%)**

___ **3.2.4 Prior Treatment:** No prior systemic treatment for NSCLC within 5 years except stage 1 and 2 cancers treated with curative intent.

___ **3.2.5** 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**.**

3.1.6 No active autoimmune disease, interstitial lung disease, or transplant that precludes safe treatment with immune checkpoint inhibitors.

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