

Protocol PACIFIC-4

International Study of Durvalumab Following Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients with unresected Stage I/II, lymph-node negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515)

This is the trial summary as assessed on clinicaltrials.gov on 10/10/2019.

Minor changes in the protocol may occur. You can check this on this direct link:

<https://clinicaltrials.gov/ct2/show/NCT03833154?term=PACIFIC-4%2FRTOG-3515&rank=1>

Trial Design:

This is a Phase III, randomized, placebo-controlled, double-blind, multi-center study assessing the efficacy and safety of durvalumab versus placebo following SoC SBRT in patients with unresected clinical Stage I/II lymph node-negative (T1 to T3N0M0) NSCLC.

Patients who complete definitive treatment with SoC SBRT and are confirmed to meet all eligibility criteria will be randomized 1:1 to durvalumab or placebo.

Key Inclusion Criteria:

Age \geq 18 years

Histologically or cytologically documented Stage I to II NSCLC, with clinical Stage I/II lymph node-negative (T1 to T3N0M0) disease and planned to receive definitive treatment with SBRT. Patients may be medically inoperable or are medically operable and refusing surgery or choosing to have SBRT (Stereotactic Body Radiation Therapy) as definitive therapy

Completion of SoC SBRT as definitive treatment prior to randomization

World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) PS of 0, 1, or 2

Life expectancy of at least 12 weeks

Body weight $>$ 30 kg

Tumor sample required

Adequate organ and marrow function required

Patients with central or peripheral lesions are eligible

Staging studies must be done within 8 weeks before randomization

Key Exclusion Criteria:

Mixed small cell and non-small cell cancer histology

History of allogeneic organ transplantation

History of another primary malignancy with exceptions

History of active primary immunodeficiency

Any unresolved toxicity National Cancer Institute (NCI) CTCAE Grade ≥ 2 from SBRT (Stereotactic Body Radiation Therapy)