

NVALT 22:

First line chemotherapy in KRAS mutated non-small cell lung cancer patients: a phase III comparing cisplatin-pemetrexed with carboplatin-paclitaxel-bevacizumab

Rationale: In a retrospective analysis of KRAS mutated non-small cell lung cancer (NSCLC) patients response and progression free survival to first line chemotherapy was better for carboplatin-paclitaxel-bevacizumab then other first line combinations.

Primary Objective: To investigate in KRAS mutated patients with incurable NSCLC whether carboplatin-paclitaxel- bevacizumab results in a prolonged progression free survival compared to cisplatin-pemetrexed as first line treatment.

Study design: Multi-center open label randomized phase III study. After stratification for KRAS mutation (G12V versus G12C versus other), performance status (0-1 vs. 2) and brain metastasis (yes of no) patients will be 1:1 randomized to carboplatin-paclitaxel-bevacizumab or cisplatin-pemetrexed.

Study population: histologically or cytologically confirmed stage IIIB or stage IV KRAS mutated NSCLC patients who are eligible for first line chemotherapy. Total accrual: 240 patients

Main study parameters/endpoints: Progression-free survival defined by the response criteria in solid tumors (RECIST).

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