

## **NVALT 10 study:**

### **Title:**

A randomized phase II study of erlotinib compared to single agent chemotherapy - erlotinib combination in pretreated patients with advanced NSCLC

### **Primary objective:**

To compare progression free survival between erlotinib and cytotoxic agent-erlotinib combination in patients who failed previous cytotoxic treatment for NSCLC locally advanced and metastatic disease in stage IIIB and IV. Pemetrexed was chosen as cytotoxic agent in non-squamous cell carcinoma and Docetaxel was chosen in squamous cell carcinoma.

### **Secondary objectives:**

To characterize the quantitative and qualitative toxicities of regimes, response rates and duration of response for responding patients, and survival.

### **Arm A:**

Erlotinib alone

### **Arm B:**

Single agent chemotherapy - erlotinib combination

- For non squamous: Arm B1: Pemetrexed + erlotinib
- For squamous: Arm B2 : Docetaxel + erlotinib

### **Start date:**

Maart 2009

### **Total:**

230 patients

### **Study Coordinators:**

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### **Centraal Data Management:**

NVALT Data Center, Amsterdam