

## **Título: Phase II Randomized Controlled Trial of an Epidermal Growth Factor Vaccine in Advanced Non–Small-Cell Lung Cancer.**

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### **Abstract**

We show the result of a randomized phase II clinical trial with an epidermal growth factor (EGF)-based cancer vaccine in advanced non–small-cell lung cancer (NSCLC) patients, evaluating immunogenicity, safety, and effect on survival.

### **Patients and Methods.**

Eighty patients with stage IIIB/IV NSCLC after finishing first-line chemotherapy were randomly assigned to receive best supportive care or EGF vaccinations.

### **Results.**

Vaccination was safe. Adverse events were observed in less than 25% of cases and were grade 1 or 2 according to National Cancer Institute Common Toxicity Criteria. Good anti-EGF antibody response (GAR) was obtained in 51.3% of vaccinated patients and in none of the control group. Serum EGF concentration showed a major decrease in 64.3% of vaccinated patients. GAR patients survived significantly more than those with poor antibody response (PAR). Also, patients whose serum EGF dropped below 168 pg/mL survived significantly more than the rest. There was a trend to an increased survival for vaccinated patients compared with controls. The survival advantage for vaccinated patients compared with controls was statistically significant in the subgroup of patients with age younger than 60 years.

## **Conclusión.**

Vaccination with EGF was safe and provoked an increase in anti-EGF antibody titers and a decrease in serum EGF. There was a direct correlation between antibody response and survival.

There was a direct correlation between decrease in serum EGF and survival. In patients younger than 60 years, vaccination was associated with increased survival.