

E1305 Clinical Trial Results Summary

Chemotherapy With or Without Bevacizumab in Treating Patients With Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

What did this trial involve and who was it for?

E1305 was for people with head and neck squamous cell carcinoma (HNSCC) whose cancer had come back and/or spread after initial treatment. HNSCC is the most common type of head and neck cancer. It affects the squamous cells that line the inside of the mouth, throat, voice box, nasal cavity, and salivary glands. At the time of the study, the usual treatment for these patients was chemotherapy—but even with chemotherapy, their survival rates were very low, with a median survival of just 6-9 months.

The purpose of E1305 was to see if adding a drug called bevacizumab to the usual treatment (chemotherapy) would help these patients live longer. Bevacizumab is a type of immunotherapy that works by blocking a protein called VEGF, which may prevent the growth of new blood vessels that tumors need to grow. At the time of the study, bevacizumab was already approved by the US Food and Drug Administration to treat other cancers, but it was not yet approved to treat head and neck cancer.

A total of 403 patients whose HNSCC had come back and/or spread after initial treatment participated in the study. Participants were randomly assigned by a computer to one of two treatment groups:

1. The standard treatment at that time: chemotherapy
2. The study approach: chemotherapy and bevacizumab

For both groups, treatment was given until the cancer worsened or stopped responding, or the side effects became too severe.

What are the results?

- There was no significant difference in overall survival between the two treatment groups.
 - Patients who received chemotherapy and bevacizumab lived approximately 12.6 months, compared with 11 months for patients who received chemotherapy alone.
- There was a significant difference in how long patients lived without their cancer getting worse.
 - Patients who received chemotherapy and bevacizumab lived approximately 6.1 months before their cancer worsened, compared with 4.4 months for patients who received chemotherapy alone.
- Patients who received chemotherapy and bevacizumab had higher rates of serious side effects than patients who received only chemotherapy. These side effects included diarrhea, fatigue, painful mouth sores, and treatment-related blood disorders.

What do the results mean for patients?

- The addition of bevacizumab to chemotherapy did not help patients with advanced HNSCC to live longer overall.
 - The addition of bevacizumab to chemotherapy did help patients to live longer before their cancer worsened, but it also caused more serious side effects.
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For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT00588770>
 - *Journal of Clinical Oncology*: <https://ascopubs.org/doi/full/10.1200/JCO.19.00555>
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About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at www.ecog-acrin.org.

To all the patients that participated in this trial, thank you. Your participation, and that of other patients like you, made this research possible.