

## E2211 Clinical Trial Results Summary

### Temozolomide With or Without Capecitabine in Treating Patients With Advanced Pancreatic Neuroendocrine Tumors

#### What did this trial involve and who was it for?

E2211 was for people with pancreatic neuroendocrine tumors (NETs) that could not be removed by surgery or that had spread beyond the pancreas. Pancreatic NETs are tumors that form in the islet cells (hormone-making cells) of the pancreas. Based on limited research, doctors most often treated patients with temozolomide chemotherapy. However, more research was needed to understand the best way to use temozolomide for these patients, including larger studies.

The purpose of E2211 was to compare treatment with temozolomide versus treatment with temozolomide plus capecitabine, to see which would help patients live longer without their cancer worsening. Capecitabine is another type of chemotherapy that was previously shown to benefit some patients with pancreatic NETs when given with temozolomide. Both drugs were already approved by the Food and Drug Administration (FDA) for use in other cancers.

A total of 144 patients with advanced pancreatic NETs participated in E2211, which was open to enrollment from April 2013 to March 2016. Participants were randomly assigned by a computer to one of two treatment groups:

1. Temozolomide given for one year, or
2. Temozolomide and capecitabine given for one year.

#### What are the results?

- Patients who received temozolomide and capecitabine lived significantly longer without their cancer getting worse than patients who received only temozolomide.
  - Patients who received both drugs had a median of 22.7 months before their cancer worsened, compared with 14.4 months for patients who received only temozolomide.
- Patients who received temozolomide and capecitabine also lived longer overall, though the difference was not large enough to be considered clinically meaningful.
  - Patients who received both drugs lived for a median of 58.7 months, compared with 53.8 months for patients who received only temozolomide.
- The combination of capecitabine and temozolomide was associated with higher rates of gastrointestinal and blood-related side effects compared with temozolomide alone.

#### What do the results mean for patients?

- The combination of capecitabine and temozolomide helped patients with advanced pancreatic NETs to live considerably longer without their cancer getting worse.
  - The combination also seemed to help patients live longer overall, but the results were not quite strong enough to say for sure that the treatment was the reason.
- This combination is now a standard treatment option for patients with advanced pancreatic neuroendocrine tumors.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT01824875>
  - *Journal of Clinical Oncology*: <https://ascopubs.org/doi/10.1200/JCO.22.01013>
  - ECOG-ACRIN Website: <https://ecog-acrin.org/ecog-acrin-research-highlights-at-asco-2022/>
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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](http://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.*