

E3F05 Clinical Trial Results Summary

Phase 3 Study of Radiation Therapy With or Without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas

What did this trial involve and who was it for?

E3F05 was for people with low-grade gliomas, a type of brain tumor. Gliomas are often, but not always, cancerous, and some types are more aggressive (high grade) than others (low grade). At the time of the study, radiation therapy was the usual initial treatment for low-grade gliomas. However, earlier research in glioblastoma (a high-grade glioma) showed that initial treatment with radiation therapy plus temozolomide (a chemotherapy drug) was more effective than radiation therapy alone. This combined approach was approved by the Food and Drug Administration (FDA) for initial treatment of glioblastomas, but additional research was needed to confirm whether it was also effective for lower-grade gliomas.

The purpose of E3F05 was to see if the addition of temozolomide to radiation therapy would help people with low-grade gliomas to live longer without their cancer worsening, compared to radiation therapy alone. A total of 172 people with low-grade gliomas participated in the study. Participants were randomly assigned by a computer to one of two treatment groups:

1. The usual approach: radiation therapy for five and a half weeks, or
2. The study approach: radiation therapy for five and a half weeks, plus temozolomide daily during radiation and for 12 four-week cycles following radiation.

E3F05 was open to enrollment from September 2009 to January 2014. The trial closed to enrollment early after another trial (RTOG 9802) showed significant benefit from adding a combination of three older chemotherapy drugs to radiation therapy for patients with low-grade gliomas.

What are the results?

- 70% of patients who received the combination therapy were still alive at 10 years after treatment, compared to 47% of patients who received radiation therapy alone.

What do the results mean for patients?

- The addition of temozolomide to radiation therapy significantly improved overall survival in patients with low-grade gliomas.
- Serious side effects were more common in patients who received temozolomide, but were similar to what had been seen in previous studies.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT00978458>
- *Neuro-Oncology*: <https://doi.org/10.1093/neuonc/noae165.1303>
- ECOG-ACRIN Press Release: <https://ecog-acrin.org/press-release-adding-the-chemotherapy-pill-temozolomide-to-radiation-therapy-improves-survival-in-adult-patients-with-glioma-a-slow-growing-type-of-brain-cancer/>

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.