

## [Canadian Cancer Trials Group CE.6 Clinical Trial published in the New England Journal of Medicine](#)

Study finds that adding temozolomide chemotherapy to short-course radiation therapy improves overall survival for older patients

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FOR IMMEDIATE RELEASE

The Canadian Cancer Trials Group (CCTG) led CE.6 phase III trial was published today in the New England Journal of Medicine. This international study tested the addition of temozolomide chemotherapy to an abbreviated course of radiation therapy in older adults with Glioblastoma (brain cancer).

“The incidence of glioblastoma is higher in the elderly population and a lack of clinical trial data in this age group has led to uncertainty about the best approaches to manage the condition,” says Dr. Chris O’Callaghan CCTG Senior Investigator. “These results will now guide both national and international practice, changing how glioblastoma is treated in elderly patients around the world.”

Lead co-authors Dr. James R. Perry (Sunnybrook Health Sciences Centre) and Dr. Normand Laperriere (UHN Princess Margaret Cancer Centre), found that the one-year and two-year survival rates were 37.8 percent and 10.4 percent with radiation plus temozolomide vs. 22.2 percent and 2.8 percent with short course radiation therapy alone.

“This study provides the first evidence from a randomized clinical trial that chemotherapy in combination with a shorter radiation schedule significantly extends survival without a detriment to quality of life,” said lead study co-author James R. Perry, Endowed Chair in Brain Tumour Research at the Odette Cancer and Sunnybrook Health Sciences Centres. “Although glioblastoma disproportionately affects older patients, there have been no clear guidelines for treating these patients, and practice varies globally.”

Glioblastoma is the most common form of brain cancer and elderly patients account for half of those diagnosed with the disease. The study demonstrates that adding the cancer drug temozolomide to a shortened course of radiation therapy, followed by monthly maintenance doses, improves the survival rate of elderly patients, reducing the risk of death by 33 percent, without loss of quality of life.

Although the difference in median survival seems modest, temozolomide significantly increased the chances of surviving two or three years. This extra time certainly means a great deal to a person with cancer and their family,” said Dr. Perry.

### **About the Study**

This international phase III trial was led by the Canadian Cancer Trials Group (CCTG) with important collaboration from the European Organization for the Research and Treatment of Cancer (EORTC) and the Trans-Tasman Radiation Oncology Group (TROG) as well as selected sites in Japan. Investigators enrolled 562 patients 65 years and older who were newly diagnosed with glioblastoma. The median patient age was 73 years and two-thirds were older

than 70 years. The patients were randomly assigned to receive either short-course radiation therapy (40Gy in 15 fractions over 3 weeks) with concurrent and adjuvant temozolomide or radiation therapy alone.

### **Key Findings**

Chemoradiation (treatment that combines chemotherapy with radiation therapy) extended the median overall survival from 7.6 months with radiation therapy alone to 9.3 months. In addition, tumour growth was slower in the temozolomide group, with median progression-free survival of 5.3 months vs. 3.9 months.

The benefit of temozolomide was greater among 165 patients with *MGMT* promoter methylation, a genetic abnormality linked to better response to temozolomide chemotherapy in this disease. In this subset of patients, the median overall survival was 13.5 months with temozolomide and 7.7 months with radiation therapy alone, a 47 percent reduction in the risk of death.

Quality of life analyses using standardized questionnaires EORTC QLQ-C30 and BN20 showed no differences in physical, cognitive, emotional, and social functioning between the two groups. However, patients who received temozolomide had more nausea, vomiting, and constipation than those who received radiation therapy alone.

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### **About the Canadian Cancer Trials Group**

[The Canadian Cancer Trials Group](#) (CCTG) is a cancer clinical trials research cooperative that runs phase I-III clinical trials to test anti-cancer and supportive therapies in over 80 institutions across Canada and more internationally. CCTG is one of the national programs of the Canadian Cancer Society Research Institute (CCSRI) and from its centre at [Queen's University](#) in Kingston, Ontario, they have supported over 500 trials in over 40 countries, aimed at improving survival rates and quality of life for all people with cancer.

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