

E1412 Clinical Trial Results Summary

Rituximab and Combination Chemotherapy with or without Lenalidomide in Treating Patients with Newly Diagnosed Stage II-IV Diffuse Large B-Cell Lymphoma

What did this trial involve and who was it for?

Diffuse large B-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma worldwide, and most patients have advanced disease by the time they are diagnosed. Unfortunately, DLBCL returns after initial chemotherapy treatment in about 40% of patients. Therefore, it is important to find better initial treatments for DLBCL in order to improve patients' long-term outcomes. The purpose of E1412 was to learn whether adding a medication called lenalidomide to the usual chemotherapy for newly diagnosed DLBCL improves patients' long-term survival. Lenalidomide has been shown to be an effective treatment for DLBCL that has returned or become resistant to treatment, but more research is needed to demonstrate its effectiveness for previously untreated DLBCL.

A total of 349 patients participated in E1412. Participants newly diagnosed with DLBCL who had not received prior treatment for their cancer were randomly assigned by a computer to one of two treatment groups: 135 patients received the usual chemotherapy, known as RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone), and 145 patients received lenalidomide in addition to their RCHOP chemotherapy; this combination was called R2CHOP. After a total of six cycles of treatment, tests were performed to assess the cancer response. Patients were monitored by their doctor regularly for up to 10 years after finishing treatment.

What are the results?

- In the R2CHOP arm, 97% of patients had at least a partial response to treatment, and 73% of patients experienced a complete response (disappearance of their cancer). In comparison, 92% of patients on the RCHOP arm had at least a partial response to treatment and 68% experienced a complete response.
- After an average follow-up time of 3 years, patients treated in the R2CHOP arm had a 34% lower risk of cancer worsening (progression) or death and an 8% higher survival rate, compared to patients in the RCHOP arm.

What do the results mean for patients?

- E1412 showed that adding lenalidomide to RCHOP for initial treatment of DLBCL improved patient outcomes. This phase 2, signal-seeking study provides important information for further studies of lenalidomide as an initial treatment of DLBCL.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT01856192>
- *Journal of Clinical Oncology*: <https://doi.org/10.1200/JCO.20.01375>

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. Without the involvement of patients like you, this research would not have been conducted.