

E1912 Clinical Trial Results Summary

Ibrutinib and Rituximab Compared with Fludarabine Phosphate, Cyclophosphamide, and Rituximab in Treating Patients with Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

What did this trial involve and who was it for?

The purpose of this trial was to compare the effects, good and/or bad, of two different treatment approaches: a combination of the drugs rituximab and ibrutinib vs. a combination of the drugs rituximab, fludarabine, and cyclophosphamide (the standard treatment). Researchers looked at the effects of these approaches for patients 70 years of age or younger with previously untreated Chronic Lymphocytic Leukemia (CLL) or small lymphocytic lymphoma (SLL), which is a subtype of CLL. A total of 529 patients participated in E1912.

What are the results?

- Two out of three people had a reduced risk of their cancer getting worse when treated with ibrutinib and rituximab.
- Patients treated with ibrutinib and rituximab were less likely to experience serious side effects than those who received the standard treatment of rituximab, fludarabine, and cyclophosphamide.

What do the results mean for patients?

- Because of these successful results, the Food and Drug Administration (FDA) approved ibrutinib and rituximab as the initial treatment for patients 70 years of age or younger with CLL.
- Ibrutinib and rituximab is now the standard first treatment for patients 70 years of age or younger with CLL, because it is more effective than standard treatment and eliminates the need for chemotherapy.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine:
<https://clinicaltrials.gov/ct2/show/NCT02048813>
- *New England Journal of Medicine*
<https://www.nejm.org/doi/full/10.1056/nejmoa1817073>

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 completed.