

EA4151 Clinical Trial Results Summary

Rituximab With or Without Stem Cell Transplant in Treating Patients with Minimal Residual Disease-Negative Mantle Cell Lymphoma in First Complete Remission

What did this trial involve and who was it for?

Mantle cell lymphoma (MCL) is a rare form of Non-Hodgkin lymphoma (NHL), representing about 6% of all NHL cases in the United States. The usual initial treatment for MCL may include chemotherapy, immunotherapy, targeted therapy, and stem cell transplantation. If initial treatment is successful, patients often have no detectable cancer remaining. This is determined based on results of imaging, bone marrow biopsy, and blood tests.

As with all types of cancer, preventing the disease from returning is important. Maintenance treatment is often given to decrease the likelihood that it may return. MCL maintenance treatment commonly includes a transplant of the patient's own stem cells (autologous stem cell transplant, or ASCT) followed by rituximab (an immunotherapy drug). ASCT helps the body replace bone marrow that may have been destroyed by prior cancer treatments; however, it is a difficult and costly procedure. The purpose of EA4151 was to determine if ASCT improves survival outcomes for patients whose MCL became undetectable after initial treatment, or if rituximab on its own would be sufficient.

650 patients with MCL whose cancer was undetectable after initial treatment participated in EA4151. Participants were randomly assigned by a computer to receive either ASCT followed by therapy with rituximab, or rituximab therapy alone.

What are the results?

EA4151 was stopped early after a planned review showed that survival outcomes were not significantly different between patients who received ASCT and rituximab versus patients who received rituximab alone.

- At follow-up, 3-year survival for patients who received ASCT and rituximab was 82.1% versus 82.7% for patients who received rituximab alone.
- Likewise, 76.6% of patients who received ASCT and rituximab remained cancer-free at 3 years versus 77.4% of patients who received rituximab alone.

What do the results mean for patients?

As treatments for MCL continue to advance, survival outcomes for patients are also improving. EA4151's results suggest that for patients with MCL that became undetectable after initial treatment, ASCT may be safely skipped without increasing the risk of their cancer returning. Longer follow-up will be important to confirm these findings.

For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine:
<https://clinicaltrials.gov/study/NCT03267433>
- *Blood*: <https://doi.org/10.1182/blood-2024-212973>

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.