

## E1411 Clinical Trial Results Summary

### Rituximab, Bendamustine Hydrochloride, and Bortezomib Followed by Rituximab and Lenalidomide in Treating Older Patients With Previously Untreated Mantle Cell Lymphoma

#### What did this trial involve and who was it for?

E1411 was for people with untreated mantle cell lymphoma (MCL), a rare, aggressive type of blood cancer that is often diagnosed in older adults and can be difficult to treat. Earlier studies showed that the drugs bendamustine, rituximab, bortezomib, and lenalidomide might be effective. The purpose of E1411 was to see which combinations of these drugs would best help patients live longer without their cancer worsening.

The trial was open to enrollment from May 2012 to September 2016 to people who had not received any previous treatment for their MCL. The majority (87%) of the 373 trial participants were over the age of 60. Patients were randomly assigned by a computer to one of four treatment groups. For the purposes of the study, the bendamustine and rituximab combination (BR) at Step 1 and rituximab only (R) at Step 2 were considered the “backbone” treatments to which bortezomib (V) and lenalidomide (L) were added for comparison.

Treatment Group	Step 1 (induction or initial treatment)	→	Step 2 (maintenance)
1	Bendamustine + rituximab (BR)	→	Rituximab (R)
2	Bendamustine + bortezomib + rituximab (BVR)	→	Rituximab (R)
3	Bendamustine + rituximab (BR)	→	Lenalidomide + rituximab (LR)
4	Bendamustine + bortezomib + rituximab (BVR)	→	Lenalidomide + rituximab (LR)

Patients received six 28-day cycles of Step 1 treatment, followed by two years of Step 2 treatment. Study treatment was discontinued if CT or PET scans showed that the MCL had worsened (progressed) or side effects became too severe. After all study treatment was completed, participants were followed by their doctor for up to 15 more years.

#### What are the results?

Initial results for the study were published in 2021, which showed no significant difference between patients who received BR and BVR at Step 1. (Results were not available for Step 2 at that time).

- 74.5% of patients who received BR and 79.6% of patients who received BVR were still alive 2 years after the start of treatment and did not experience cancer progression (this is referred to as progression-free survival).

Further results, which included the Step 2 data, were published in 2024 and showed no significant difference in progression-free survival between the four treatment groups:

- At 5 years after starting treatment, progression-free survival was 61.2% for patients in Group 1 (BR+R); 56.5% for patients in Group 2 (BVR+R); 55.3% for patients in Group 3 (BR+LR); and 68.3% for patients in Group 4 (BVR+LR). The differences between the two groups were not considered statistically significant, meaning that the data could not confirm whether the differences were due to the different treatments rather than random chance.

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## What do the results mean for patients?

- Adding bortezomib (V) to Step 1—or lenalidomide (L) to Step 2—did not significantly improve progression-free survival. The combination of bendamustine and rituximab as initial treatment, followed by rituximab for the maintenance phase, was shown to be effective for treating MCL overall.
- More research is needed to continue improving treatments for patients with MCL, especially for older patients.

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For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine:  
<https://clinicaltrials.gov/study/NCT01415752>
- *Journal of Clinical Oncology* (2021):  
[https://ascopubs.org/doi/10.1200/JCO.2021.39.15\\_suppl.7503](https://ascopubs.org/doi/10.1200/JCO.2021.39.15_suppl.7503)
- *Blood* (2024): <https://doi.org/10.1182/blood.2024023962>

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## 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](http://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.***