

Rituximab and fludarabine produce long-term remissions in CLL

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New research shows that a less-toxic combination of a targeted immune-based drug and a chemotherapy drug can produce long-term remissions in some chronic lymphocytic leukemia patients. And it does so without increasing the risk of later therapy-related myelodysplastic syndrome and acute myeloid leukemia, which can often occur with a three-drug combination used to treat these patients.

The multi-institutional study, led by researchers at the Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, reports on the outcomes of 104 people with chronic lymphocytic [leukemia](#) (CLL) who were treated with the targeted agent rituximab and the chemotherapeutic drug fludarabine.

After nearly 10 years of follow-up, 13 percent of patients had remissions lasting more than seven years, and patients with certain genetic features in their CLL cells achieved long-term remission even when a small amount of disease remained after initial therapy.

"Our study shows that remissions of more than 10 years can be attained by combining fludarabine and rituximab in CLL without risk of secondary leukemia," says principal investigator Dr. John Byrd, director of the division of hematology, D. Warren Brown Chair of Leukemia Research and professor of medicine, of medicinal chemistry and of veterinary biosciences.

"We also identified prognostic factors at the time of diagnosis that predict long-term survival, which should allow us to predict which patients will most benefit from this regimen," he adds.

All patients were treated through a national clinical trial sponsored by the Cancer and Leukemia Group B (CALGB), a clinical cooperative group. The findings were reported online in the *Journal of Clinical Oncology*.

First author Dr. Jennifer Woyach, a hematology researcher at the OSUCCC – James, notes that the findings are important because fludarabine plus rituximab and fludarabine plus cyclophosphamide and rituximab are the two most common regimens used to treat CLL.

"We learned from this study that many patients with low-risk disease will have excellent outcomes with the two-drug combination, so they can be spared the toxicity that comes with the addition of cyclophosphamide. In addition, we show that it is possible to achieve long-term remission without completely eliminating the disease, which challenges the existing belief that it is necessary to completely eradicate the disease for long-term remission in low-risk patients.

"Importantly, we show that, unlike the three-drug combination, fludarabine plus rituximab does not increase the risk of therapy-related acute leukemias in CLL patients," she says. "This is important because these malignancies are difficult to treat and have an extremely poor prognosis."

Provided by Ohio State University Medical Center

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