

Clinical trial results show new drug is better for CLL patients

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Older adults with chronic lymphocytic leukemia may have an alternative to toxic chemotherapy as their first treatment, according to a national study to be reported online Dec. 6, 2015, in the *New England Journal of Medicine* and co-authored by a Wilmot Cancer Institute oncologist.

The phase 3 clinical trial compared a newer, targeted drug, ibrutinib, against chlorambucil, a type of chemotherapy usually given to CLL [patients](#) as a front-line therapy. Paul Barr, M.D., director of the Clinical Trials Office at Wilmot, which is part of the University of Rochester Medical Center, supervised trial enrollment for patients in the Rochester and Finger Lakes region of upstate New York.

Scientists have been searching for an alternative treatment for CLL because this type of blood cancer often afflicts people in their 70s who have other medical problems and are more likely to be harmed by the toxicity of standard chemo. Ibrutinib is currently approved to treat CLL patients who have already received at least one other drug—but this was the first study to test its use as an initial therapy.

Results showed that among 269 patients with a median age of 73, ibrutinib was superior to chlorambucil in each measured aspect, including progression-free survival, overall response rate, and overall survival. Another key result: ibrutinib appeared to restore bone marrow function, which is relevant since bone marrow failure is a significant problem in CLL.

The risk of death or disease progression was 84 percent lower in the patients who took ibrutinib, compared to chlorambucil. It also extended survival, with about 98 percent of patients still alive two years after starting the targeted drug, versus 85 percent of the chlorambucil patients.

Difficult side effects occurred in about 20 percent of the patients taking ibrutinib, including diarrhea, fatigue, cough, nausea. However, 87 percent of patients were able to continue taking the drug for the median follow-up period of 18.4 months. The chlorambucil patients also experienced similar side effects, although early discontinuation of the chemotherapy [drug](#) due to complications was more than twice as frequent, the study said.

Provided by University of Rochester Medical Center

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