

Treating the TOTAL patient: clinical trial reduces relapse

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Sima Jeha, M.D., of the St. Jude Departments of Oncology and Global Pediatric Medicine, and Ching-Hon Pui, M.D., chair of the St. Jude Department of Oncology, led a St. Jude clinical trial that reduces relapse in patients with acute lymphoblastic leukemia. Credit: St. Jude Children's Research Hospital

Despite modern therapies, 10% of patients with acute lymphoblastic

leukemia (ALL) treated in the U.S. relapse, which dramatically reduces their chance of survival. Results from a St. Jude Children's Research Hospital clinical trial reduced the rate of central nervous system (CNS) relapse. These findings, from the Total Therapy Study 16, appear as an advance online publication today in the *Journal of Clinical Oncology*.

Total 16 evaluated interventions aimed at preventing relapse by improving systemic and CNS disease control. Researchers found that adding doses of chemotherapy in the [cerebrospinal fluid](#) earlier in care improved CNS control without adding toxicity for high-risk patients.

On the predecessor clinical trial (Total 15), the rate of CNS relapse for [high-risk patients](#) was 5.7%. Under Total 16, the rate of CNS relapse for a similar group of patients was reduced to 1.8%, the lowest among reported studies. As in Total 15, no patient received prophylactic cranial radiation. These results further supported the conclusion of Total 15 that all children with [acute lymphoblastic leukemia](#) can be safely spared prophylactic cranial radiation.

"In [cancer research](#), leukemia always leads the way," said corresponding author Ching-Hon Pui, M.D., St. Jude Department of Oncology chair.

"St. Jude is at the forefront of a new era of cancer treatment where therapies are optimized to provide the maximum benefit to all patients in terms of survival and quality of life, even those at the highest risk."



Ching-Hon Pui, M.D., St. Jude Department of Oncology, with a St. Jude patient who is now enrolled in Total Therapy Study 17, which introduces novel molecular targeted and immunotherapies, including CAR-T cells. Credit: St. Jude Children's Research Hospital

ALL, which affects [white blood cells](#), is the most common form of childhood cancer. In the U.S., 90% of patients are cured of their disease. Total 16 enrolled 598 patients age 18 and younger from 2007-2017. This study included all subtypes of ALL, including B-ALL and T-ALL, those with Philadelphia chromosome rearrangements, and infant leukemia, among others.

"In addition to relapse, infections and other treatment complications are the things that keep physicians up at night," said first author and principal investigator of the study Sima Jeha, M.D., of the St. Jude Departments of Oncology and Global Pediatric Medicine. "Our work will continue until the day when every patient can thrive after treatment."

The next St. Jude clinical trial for ALL, Total 17, continues to stratify patients based on their risk of relapse and introduces novel molecular targeted and immunotherapies, including CAR-T cells.

Provided by St. Jude Children's Research Hospital

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