

Researchers conduct largest clinical trial seeking to prevent heart failure among childhood cancer survivors

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Physicians at City of Hope in cooperation with the Children's Oncology Group (COG), have conducted the largest clinical trial to date seeking to reduce the risk of people who have survived childhood cancer from developing heart failure. The findings <u>published</u> in *The Lancet Oncology* show that the blood vessel relaxing medication carvedilol is safe for childhood cancer survivors to take and may improve important markers of heart injury sustained as a result of chemotherapy exposure.

One devastating long-term side effect from a class of chemotherapy called anthracycline is increased risk of heart failure where the heart can't pump enough blood to meet the body's needs. This is a delayed process where the heart undergoes gradual changes over time characterized by the thinning of the heart muscle and enlargement of its chambers. Unfortunately, after the onset of heart function decline, the downward cascade is irreversible, highlighting an urgent need for early prevention strategies.

"The growing number of <u>childhood cancer</u> survivors makes the development of early interventions imperative. Just helping children survive cancer isn't enough. We also need to optimize patients' health so that they don't have to face life-threatening side effects decades after they are cancer free," said Saro H. Armenian, D.O., M.P.H., Barron Hilton Chair in Pediatrics at City of Hope Children's Cancer Center and corresponding author of *The Lancet Oncology* study.

Physicians from City of Hope led the randomized, double-blind Phase IIb clinical trial conducted at 30 COG-member hospitals in the United States and Canada (COG Study ID: ALTE1621). Some 182 enrolled participants took relatively low doses of carvedilol or equivalent placebo for two years. There were no significant differences in side effects between the two study arms, and carvedilol appeared to be well-tolerated.



Although the clinical trial did not achieve its goal of decreasing the thinning of the heart muscle and enlargement of its chambers, there were significant improvements in heart left ventricular end-systolic wall stress, which is an earlier biomarker of worsening heart health.

"The greatest benefit was seen in participants who were very long-term survivors, as well as in those who were highly adherent to the study medication. Moreover, of the eight patients who developed clinically significant decline in heart function while on the study, six were randomized to placebo and two were receiving carvedilol," Armenian said.

"Our research sets the stage for a Phase III clinical trial that may demonstrate a significant benefit for certain patients who are at an especially high risk of irreversible heart function decline after completion of cancer therapy."

Douglas S. Hawkins, M.D., COG group chair and a hematology-oncology professor at Seattle Children's Hospital, added, "Conducting this study across 30 institutions and among long-term survivors of childhood cancer illustrates the strengths of the COG network. An intervention study on this scale would not be feasible outside of COG. Future research will need to focus on the optimal timing, duration and population for carvedilol intervention."

This study is an important first step toward developing future studies that will seek to optimize the long-term well-being and health of survivors who are expected to live for decades after their initial cancer diagnosis.

More information: Saro H Armenian et al, Effect of carvedilol versus placebo on cardiac function in anthracycline-exposed survivors of childhood cancer (PREVENT-HF): a randomised, controlled, phase 2b trial, *The Lancet Oncology* (2024). DOI:



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