

Multi-center clinical study intensifies first strike at high-risk cancer in kids

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An experimental treatment that combines intense chemotherapy with a radioactive isotope linked to synthesized neurotransmitter is being tested in newly diagnosed cases of high-risk neuroblastoma – a deadly, hard-to-cure childhood cancer.

The experimental radiopharmaceutical, 131I-MIBG, has already been tested in children with relapsed and resistant neuroblastoma, with encouraging results in reducing tumor size. This has prompted doctors in a new multi-center pilot clinical trial to see if their innovative combination therapy can help improve cure rates for newly diagnosed children and young adults, according to Brian Weiss, MD, trial chair and an oncologist at the Cincinnati Children's Hospital Medical Center.

Cure rates for neuroblastoma have plateaued at about 40 percent and new solutions are needed to improve outcomes, said Weiss, a member of the medical center's Cancer and Blood Diseases Institute.

"Unlike some diseases, there is no single detectable biological sign of neuroblastoma, so it's hard to catch early," he explained. "Children with relapsed disease usually don't survive more than a few years. We want to see if giving this more intensive treatment right after diagnosis will safely decrease the chances of the cancer coming back."

Neuroblastoma is one of the most commonly diagnosed childhood cancers, developing in nerve cells outside the brain. The cancer is usually first diagnosed by showing up as a lump or mass in the belly, or near the



spinal cord in the chest or neck. The disease can spread to bone, the liver, lymph nodes and bone marrow. In high-risk neuroblastoma, the tumor has often spread from its primary site and is harder to treat.

MIBG stands for Meta-Iodo-Benzyl-Guanidine, a synthesized form of the adrenal gland hormone and <u>neurotransmitter</u> adrenalin. MIBG concentrates selectively in the body's sympathetic nervous system, which helps control glands and muscles. When attached to the radioactive isotope iodine-131, it's known as 131I-MIBG. After being injected, 131I-MIBG targets and is taken up by nerve tumors like neuroblastoma. This exposes the cancer cells to very high doses of radiation from the iodine-131, with minimal toxicity to neighboring normal cells.

Standard treatment for neuroblastoma normally includes several rounds of chemotherapy combined with surgery and external radiation. In the current trial, a round of chemotherapy will be replaced by injection of 131I-MIBG combined with the chemotherapy drugs vincristine and irinotecan. The chemotherapy drugs will kill some of the cancer cells and, according to research, may help 131I-MIBG do a better job of eradicating tumor cells, said Weiss.

Patients receiving the treatment will also receive a transfusion of previously collected blood stem cells to boost their blood counts after being injected with the <u>radioactive isotope</u>.

The trial is coordinated through and sponsored by the Children's Oncology Group (COG), an international research consortium of the National Cancer Institute (National Institutes of Health). Thirteen hospitals in the United States and Canada are currently participating in the trial, which is expected to last two years and include up to 44 newly diagnosed patients who have not received previous treatment for their neuroblastoma.



Data from the trial, considered a small pilot study, will be used to help inform larger subsequent clinical trials testing 131I-MIBG-vincristine-irinotecan therapy for neuroblastoma, according to Weiss. The pilot trial's initial goal is determining the feasibility of newly diagnosed patients traveling from a participating home/regional medical center to participating specialized centers that will administer the 131I-MIBG part of therapy, and then back to their home center for the remainder of treatment.

Four of the 13 currently participating hospitals will administer the 131I-MIBG portion of the therapy, which requires special capabilities: Cincinnati Children's, Children's Hospital of Philadelphia, University of California-San Francisco School of Medicine, and C.S. Mott Children's Hospital in Ann Arbor, Mich.

Other participating hospitals include: Phoenix Children's Hospital, Medical University of Southern Carolina, University of Texas Southwestern Medical Center, Children's Hospital Los Angeles, The Children's Hospital Denver, Children's National Medical Center, Primary Children's Medical Center, Salt Lake City, University of Chicago, and University of Alabama, Birmingham. Two additional medical centers are expected to be added to the trial, Weiss said.

Provided by Cincinnati Children's Hospital Medical Center

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