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Antibody drug sharply reduces risk of severe chronic graft-versus-host disease in patients undergoing allogeneic stem cell transplant, trial shows

- Transplant recipients treated with B cell-depleting drug obinutuzumab had far lower incidence of chronic GVHD requiring treatment with systemic steroids

SAN DIEGO -- In patients who have undergone a donor stem cell transplant, preventative treatment with the drug obinutuzumab can sharply reduce the risk of developing chronic graft-versus-host disease (cGVHD) severe enough to require treatment with systemic steroids, a clinical trial led by Dana-Farber Cancer Institute investigators indicates.

The findings, to be presented at the 65th American Society of Hematology Annual Meeting and Exposition, reinforce the effectiveness of drugs that, like obinutuzumab, deter cGVHD by depleting the body's supply of B cells – white blood cells that can contribute to the etiology of the disease. Patients who receive a transplant of allogeneic (donor) stem cells can develop cGVHD if the transplanted cells recognize their new host as foreign and launch an attack on healthy tissue.

The trial enrolled 181 patients who had undergone a donor peripheral blood stem cell transplant followed by treatment with the drug tacrolimus to prevent acute GVHD. Participants were randomly selected to receive either a placebo or four doses of obinutuzumab over the course of the next year. In the first year after transplant, only 11% of those treated with obinutuzumab developed cGVHD that required systemic steroid treatment, compared to 38% of those taking a placebo. At the two-year mark, the rate of steroid-requiring cGVHD remained lower in the obinutuzumab group – 28%, compared to 44% for the placebo group.

Investigators report that obinutuzumab was well tolerated and associated only with transient neutropenia.

In conjunction with the trial, researchers led by co-senior authors Jerome Ritz, MD, of Dana-Farber and David Miklos, MD, PhD, of Stanford University Medical Center measured the development of antibodies to H-Y minor antigens in 65 male participants. Such antibodies are a major cause of cGVHD in female-to-male transplantation. Twelve months after the start of the trial, these antibodies were found in just 12.5% of patients treated with obinutuzumab, compared to 36.7% in the placebo group. Among patients receiving obinutuzumab, those who had no or low levels of H-Y antibodies when trial began were far less likely to develop steroid-requiring cGVHD than all other participants – 13% vs. 57%. The findings suggest that low levels of these antibodies may be a biomarker for patients who are most likely to benefit from obinutuzumab.

“Since cGVHD is a major cause of morbidity after allogeneic stem cell transplant, we are very excited to have a new, safe, and effective way to prevent cGVHD,” said study lead author [Corey Cutler, MD](#), of Dana-Farber Cancer Institute. “Our patients will benefit tremendously from this novel therapeutic.”

Funding was from NHLBI, and Genentech provided the study compound.

About Dana-Farber Cancer Institute

[Dana-Farber Cancer Institute](#) is one of the world’s leading centers of cancer research and treatment. Dana-Farber’s mission is to reduce the burden of cancer through scientific inquiry, clinical care, education, community engagement, and advocacy. Dana-Farber is a federally designated Comprehensive Cancer Center and a teaching affiliate of Harvard Medical School.

We provide the latest treatments in cancer for adults through [Dana-Farber Brigham Cancer Center](#) and for children through [Dana-Farber/Boston Children’s Cancer and Blood Disorders Center](#). Dana-Farber is the only hospital nationwide with a top 5 *U.S. News & World Report* Best Cancer Hospital ranking in both adult and pediatric care.