

Inhibitor development risk similar for factor VIII products

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For children with severe hemophilia A, the risk of inhibitor development is similar with plasma-derived and recombinant factor VIII products and is not affected by von Willebrand factor content or by switching among products, according to research published in the Jan. 17 issue of the *New England Journal of Medicine*.

(HealthDay)—For children with severe hemophilia A, the risk of inhibitor development is similar with plasma-derived and recombinant factor VIII products and is not affected by von Willebrand factor content or by switching among products, according to research published in the Jan. 17 issue of the *New England Journal of Medicine*.

Samantha C. Gouw, M.D., Ph.D., of the University Medical Center Utrecht in the Netherlands, and colleagues examined the effects of specific <u>factor VIII</u> product administration on the development of clinically relevant inhibitory antibodies in 574 consecutive children with severe hemophilia A, born from 2000 to 2010.



The researchers found that the cumulative incidence of inhibitory antibody development was 32.4 percent, while a high-titer inhibitory antibody, defined as a peak titer of at least 5 Bethesda units/mL, had a cumulative incidence of 22.4 percent. The risk of inhibitor development was similar for plasma derived or recombinant products. Among the recombinant products, however, second-generation full-length products correlated with a significantly increased risk of inhibitor development (adjusted hazard ratio, 1.6) compared with third-generation products derived from the full-length <u>complementary DNA</u> sequence of human factor VIII. The risk of inhibitor development was not associated with the von Willebrand factor content of products or switching between products.

"Recombinant and plasma-derived factor VIII products conferred similar risks of inhibitor development, and the content of von Willebrand factor in the products and switching among products were not associated with the risk of inhibitor development," the authors write. "Second-generation full-length recombinant products were associated with an increased risk, as compared with third-generation <u>products</u>."

The study was funded by Bayer Healthcare and Baxter BioScience; several authors disclosed financial ties to pharmaceutical companies, including Bayer and Baxter.

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