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SIPPET study may have implications for treatment of patients with severe hemophilia A

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SIPPET, a study which involved 42 centers in 14 countries in Europe, North and South America, Africa and Asia was designed to definitively settle the long-debated question whether factor VIII concentrates from different sources (plasma-derived containing VWF or recombinant technology) differ in risk of inhibitor development in previously untreated children (PUPs) with severe hemophilia A.

What makes SIPPET unique is that it is the first randomized study in which patients were randomly assigned to receive either plasma-derived FVIII/VWF or recombinant factor VIII concentrates. Randomized studies are considered by physicians to provide the highest level of evidence, since randomization minimizes confounding factors that could bias the outcome.

The study was conducted between 2010 and 2015. Of the 251 patients analyzed, 76 developed an inhibitor. Twenty-nine of the 125 patients in the plasma-derived arm and 47 of the 126 patients in the recombinant arm developed an inhibitor - the primary study endpoint. Cox regression analysis demonstrated that the treatment of PUPs with severe hemophilia A with recombinant factor VIII was associated with an 87% higher incidence of inhibitors than treatment with plasma-derived factor VIII/VWF. Similar results were found for the development of high-titre inhibitors.

The results, published in the May 26 issue of the New England Journal of Medicine, may have implications for the choice of products to treat patients, since the development of inhibitors remains the major challenge in the management of hemophilia A.

Source:
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