An international randomized controlled study reports a higher incidence of inhibitors with recombinant factor VIII than plasma-derived factor VIII containing von Willebrand factor in previously untreated patients with hemophilia A

- The Angelo Bianchi Bonomi Foundation is pleased to announce that the SIPPET (Survey of Inhibitors in Plasma-Products Exposed Toddlers), the first randomized and controlled study on hemophilia and inhibitors designed to answer a key clinical question regarding the role that the product source plays in the development of inhibitors, has been completed.

- The results of the study have been selected for presentation in the prestigious and highly selective Plenary Session at the congress of the American Society of Hematology and were presented in Orlando on December 6th, 2015 at 2 PM.

- The results may have implications in the choice of products for management in previously untreated patients (PUPs) with severe hemophilia A.

- SIPPET is an investigator-driven study sponsored by the Angelo Bianchi Bonomi Foundation that obtained financial support from the Italian Ministry of Health and unrestricted grants from Grifols, Kedrion and LFB.

*Milan, December 7th, 2015.* SIPPET, a study involving 42 sites and 14 countries in 5 continents began to definitely answer – for the first time through the scientific and rigorous approach of a randomized clinical trial – whether the source of factor VIII (FVIII) replacement (plasma derived, pd; or recombinant, r) affects the rate of inhibitory antibodies in previous untreated patients (PUPs) with severe hemophilia A.

According to the results from the SIPPET study led by the investigators Flora Peyvandi and Pier M. Mannucci, from the Angelo Bianchi Bonomi Hemophilia and Thrombosis Center of Milan (Italy), the treatment of severe hemophilia A with recombinant factor VIII (rFVIII) is associated with an 87% higher incidence of inhibitors than treatment with plasma-derived factor VIII containing von Willebrand factor (pdFVIII/VWF). The results were presented at the Annual Meeting of the American Society of Hematology in Orlando, FL (United States) and according to Prof. Peyvandi, “they may have implications for the choice of products to treat PUPs, since the development of inhibitors remains the major challenge in the management of hemophilia A”.

Hemophilia A is a coagulopathy characterized by the deficiency of coagulation factor VIII. It can be treated by replacing factor VIII from either a plasma-derived or recombinant source. SIPPET was designed to establish whether or not the source of product affects the rate of inhibitors in previously untreated patients (PUPs) with severe hemophilia A. It is the first randomized controlled study on hemophilia A and inhibitors and is reflective of clinical practice using current treatments worldwide.
Investigators conducted the study between 2010 and 2015, and included 251 patients. 76 patients developed an inhibitor, of whom 50 presented high titers. 90% of inhibitors developed in the first 20 days of treatment.

SIPPET is an investigator-driven, international, multicenter, prospective, randomized, open label, study, sponsored by the Angelo Bianchi Bonomi Foundation. It obtained financial support from the Italian Ministry of Health and unrestricted grants from Grifols, Kedrion and LFB.

Further information:

SIPPET abstract: https://ash.confex.com/ash/2015/webprogram/Paper82866.html

SIPPET website: http://www.sippet.org