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XXIst Congress of
the International
Society on
Thrombosis and
Haemostasis



ISTH 2007

Geneva, Switzerland – 6-12 July 2007

XXIST CONGRESS OF THE INTERNATIONAL SOCIETY ON THROMBOSIS AND HAEMOSTASIS
53rd Annual Meeting of the Scientific and Standardization Committee (SSC)

Official Press Release

ISTH CONGRESS HIGHLIGHTS: Continuous peri-operative infusion of antithrombin alfa normalises VTE risk in patients with hereditary anti-thrombin deficiency; Oral dabigatran can prevent VTEs in hip surgery patients

Continuous peri-operative infusion of antithrombin alfa normalises VTE risk in patients with Hereditary Anti-thrombin Deficiency

Geneva, 11 July 2007: Continuous infusion of transgenically produced antithrombin alfa (Atryn®) during surgery can normalise the risk of thrombosis in patients with Hereditary Anti-thrombin (AT) Deficiency, according to data presented at the XXIST Congress of the International Society on Thrombosis and Haemostasis, by Dr Campbell Tait, Consultant Haematologist, Glasgow Royal Infirmary, Scotland, UK.

Patients with this rare disorder have reduced AT plasma activity, which renders them 10-50 times more likely to develop a thromboembolic event. Consequently, up to 80% of patients suffer an event during their lifetime, yet in high-risk situations such as surgical procedures, therapeutic doses of anticoagulants are often contra-indicated.

The 15-patient, pharmacokinetic study found that by continually infusing antithrombin alfa, AT activity levels were normalised to, and maintained at, a target activity rate of 80-120%. The risk of thrombosis was also therefore normalised.

The prevalence of Hereditary AT Deficiency is estimated at 0.02%.

Oral dabigatran can prevent VTEs in hip surgery patients

Dabigatran, a novel reversible, oral direct thrombin inhibitor, can prevent venous thromboembolisms (VTEs) as effectively and safely as subcutaneous enoxaparin, according to phase III data presented today at the XXIST Congress of the International Society on Thrombosis and Haemostasis, Geneva, Switzerland.

During this 'RE-NOVATE' study, 3,494 patients undergoing total hip replacement were randomized to receive once-daily doses of dabigatran 150 mg, dabigatran 220 mg, or enoxaparin 40 mg. The median duration of treatment was 33 days, and the study's primary efficacy outcome was a composite of total VTE and death from all causes. Major bleeding rates were also assessed.

The study data showed that:

- dabigatran was as effective as enoxaparin for preventing VTE and all-cause mortality (8.6% in the dabigatran 150 mg arm, 6.0% in the dabigatran 220 mg arm, and 6.7% in the enoxaparin 40 mg arm);
- dabigatran and enoxaparin were associated with similarly low major bleeding rates (1.3% in the dabigatran 150 mg arm, 2.0% in the dabigatran 220 mg arm, and 1.6% in the enoxaparin 40 mg arm);
- the incidence of liver enzyme elevations and acute coronary events during treatment and follow-up did not differ significantly between groups.

Speaking on behalf of the RE-NOVATE Study Group, Dr Bengt Eriksson, Orthopaedic Surgeon, Sahlgrenska University Hospital, Göteborg, Sweden, and lead study investigator said: "The positive efficacy and safety data for dabigatran etexilate in preventing potentially life-threatening VTEs after hip and knee replacement surgery signals a therapeutic advantage which will be welcomed by both physicians and patients in the future."

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NOTES TO JOURNALISTS

About the ISTH

The ISTH is a non-profit organization with over 2,800 members from more than 70 countries. The International Society on Thrombosis and Haemostasis, Inc. is organized and operated exclusively for scientific and educational purposes. Its objectives are to foster and advance science relating to the important medical problems of thrombosis and abnormalities of haemostasis and vascular biology; to provide a forum for discussion of these problems; to encourage research on these problems by scientists of the several relevant disciplines; to foster the diffusion and exchange of ideas through scientific meetings and publications; to standardize nomenclature and methods as appropriate and timely.

The ISTH sponsors a peer-reviewed medical journal as part of its mission to advance knowledge, to provide a forum for discussion among the leading experts in the areas of thrombosis, haemostasis and vascular biology and to foster the diffusion and exchange of ideas through high-quality scientific publications. This monthly publication, entitled *The Journal of Thrombosis and Haemostasis: Official Journal of the International Society on Thrombosis and Haemostasis*, is distributed free-of-charge to all ISTH members.

The next bi-annual Congress of the ISTH will be held in Boston, MA, USA on 11-17 July, 2009. Further details can be found at: <http://www.med.unc.edu/isth/>

Additional information about the ISTH including the various ISTH-supported clinical registries and databases, can be found at the ISTH website:

<http://www.med.unc.edu/isth/>

Additional information about the XXIST Congress of the ISTH can be found at

<http://www.isth2007.com/>