Press Release

New study shows that extending prophylaxis with Clexane® (enoxaparin sodium injection) to five weeks is more effective than 10 days for reducing the risk of Venous Thromboembolism (VTE) in acutely ill medical patients with reduced mobility

- EXCLAIM is the first international study to show that extended thromboprophylaxis reduces VTE risk in acutely-ill medical patients with a statistically significant 44% -

Sanofi-aventis recently announced the results of the EXCLAIM (EXtended CLinical prophylaxis in Acutely Ill Medical patients) study, which showed the benefit of extended prophylaxis in acutely ill medical patients with reduced mobility by demonstrating the superiority of five weeks course of prophylaxis with Clexane® compared to 10 days regimen with a statistically significant 44% reduction in venous thromboembolism (VTE) events (Deep Vein Thrombosis and / or Pulmonary Embolism). The findings were presented at the XXIst ISTH Congress (International Society on Thrombosis and Haemostasis) in Geneva, Switzerland.

Acutely ill medical patients are at high risk of VTE. The benefit of thromboprophylaxis with enoxaparin (10±4 days) has already been demonstrated in this patient population and is considered as the standard regimen[1]. Nonetheless clinical practice suggests that the risk of VTE may continue beyond 10 days[1] particularly in patients with reduced mobility. The efficacy and safety of extended prophylaxis in this medical population had never been assessed although it has been demonstrated for several high-risk surgical patient populations[2;3] and therefore recommended by international guidelines[4].

The objective of EXCLAIM study was to assess the superiority of enoxaparin prophylaxis given for 28± 4 days versus placebo, both following an initial treatment with enoxaparin for 10±4 days, to reduce VTE events rate. The primary efficacy endpoint was the incidence of asymptomatic deep-vein thrombosis (DVT), symptomatic DVT, symptomatic pulmonary embolism (PE), or fatal PE during the double-blind period.

The statistically significant 44% relative risk reduction in VTE events observed for extended-duration prophylaxis with enoxaparin versus placebo for the primary endpoint (2.8% vs. 4.9%; p=0.0011) was associated with a reduction in symptomatic VTE by 73% (0.3% vs. 1.1%; p=0.0044) and asymptomatic proximal DVT by 34% (2.5% vs. 3.7%; p=0.0319). No statistically significant differences were observed for symptomatic pulmonary embolism (PE) or fatal PE. The statistically significant relative risk reduction of VTE observed with enoxaparin at 38 days was maintained at 90 days (3.0% vs. 5.2%; p=0.0015).

Victor F. Tapson, MD, Professor of Medicine, Director, Center for Pulmonary Vascular Disease, Division of Pulmonary and Critical Care, Duke University Medical Center, Durham, NC, and a lead investigator of the EXCLAIM study said: "*What the trial results showed is that patients do not leave their risk for VTE at the door when they leave the hospital. With continued prophylaxis,* Clexane® *statistically significantly reduced the risk by 44% in acutely ill medical patients with prolonged immobility.*"

In comparison with placebo, the rate of major bleeding was statistically significantly higher in the extended enoxaparin arm (0.6% vs. 0.15%, p=0.019), but the overall event rate was low. There was no difference in all-cause mortality between extended enoxaparin versus placebo at 6 months (10.1% vs. 8.9%; p=0.18).

"*EXCLAIM is the first study to assess the benefit of extended thromboprophylaxis in acutely ill medical patients with reduced mobility and to demonstrate the clinical benefit of five weeks enoxaparin treatment versus 10 days in this patient population*" said Professor Russell Hull from the University of Calgary, Canada and Chair of the Steering Committee for the EXCLAIM study. "*Similarly to the initial demonstration of the benefit of thromboprophylaxis for acutely ill medical patients, first established by the MEDENOX trial, the EXCLAIM study should be a landmark trial in advancing the standard of care of patients at high risk for VTE and it further establishes enoxaparin as a reference treatment for VTE prophylaxis in acutely ill medical patients".*

About EXCLAIM

The EXCLAIM trial is the first international, multicenter, prospective, randomised, double-blind, placebo-controlled study. It enrolled 5,105 acutely-ill patients with recent reduced mobility in 20 countries, comparing extended-duration (28± 4 days) venous thromboembolism (VTE) prophylaxis with enoxaparin, a low-molecular-weight heparin (LMWH) with the standard regimen of enoxaparin (10±4 days) for the prophylaxis of VTE.

Patients recently immobilised for up to three days with level 1 mobility (total bed rest or sedentary patients) or with level two mobility (with bathroom privileges) with age > 75 years or history of VTE or diagnosis of cancer and predefined acute medical illness were randomised to received enoxaparin 40 mg subcutaneously once daily for 10±4 days and were then randomised to receive the same enoxaparin regimen or placebo for an additional 28± 4 days.

The steering committee followed the Data Safety Monitoring Board (DSMB) suggestion that in addition to level 1 mobility patients to re-define the inclusion criteria by adding on level 2 mobility patients inclusion criteria : Age >75 years, or prior VTE or diagnosed cancer.

The objective of the EXCLAIM study was to assess the superiority of enoxaparin prophylaxis given for 28± 4 days versus placebo, both following an initial treatment with enoxaparin for 10± 4 days, to reduce VTE events.

The primary efficacy endpoint was the incidence of asymptomatic deep-vein thrombosis (DVT) detected by routine standardised ultrasonography, symptomatic DVT, symptomatic pulmonary embolism (PE), or fatal PE during the double-blind period. Secondary efficacy endpoints include the incidence of VTE at three months and the incidence of mortality up to six months after enrolment.

The primary safety endpoint was major hemorrhagic complications during the same period.

References

1. Samama.New England Journal of Medicine.Sept.1999.
2. Bergqvist New England Journal of Medicine March 2002/ Vol 346, N°13.
3. Hull, Ann Intern Med.2001; 135:858-869.
4. Geerts.Chest.2004.

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Press Release

Travel Medicine Conference

Friday 26 to Sunday 28 October 2007

Kopanong Hotel & Conference Centre
Johannesburg, South Africa
(011) 749 0000 www.kopanong.co.za

Do not miss this opportunity of knowing how to safe-guard the traveller from the potential hazards of travel. It will be a fun-filled adventure as SASTM is fortunate to have Dr Ron Behrens from the Tropical School of Medicine, London, address many of the common problems encountered by travellers. The formal lectures and interactive workshops will provide an excellent opportunity to ensure that your knowledge is current.

Topics include: Travel Medicine in Southern Africa, Dilemmas in Travel Medicine, Respiratory Tract Infections and Travel, Common Travel Medicine Problems, The Returning Traveller, Drug Interactions in Travel Medicine, TB and Air Travel, The Immunocompromised Traveller, Principles of Evacuation, Women and Travel, Malaria, Malaria Control, Programmes in Mining Situations, The Travel Bug

Accredited for CPD points

Visit the SASTM website www.sastm.org.za
& click on Travel Medicine Updates to register now!

Press Release

International speaker to address the importance of calcium supplementation in teenagers to ensure lifelong bone health

It is estimated that 40% of women will suffer an osteoporosis fracture in their lifetime. The cost of osteoporosis exceeds $30 billion worldwide. The only cost-effective approach to osteoporosis is prevention.

To raise awareness around Osteoporosis Day 20 October 2007, Wyeth Consumer Healthcare will host the internationally renowned Professor Connie Weaver, together with South African specialists, on a lecture tour addressing the South African medical fraternity.

Prof Weaver is a distinguished Professor and Head of the Foods and Nutrition Department at Purdue University in the United States and has conducted several groundbreaking research studies on calcium metabolism, including a landmark study finding that calcium absorption peaks in young girls near the onset of menses. The research provided insight into factors affecting development of peak bone mass during growth, which determines the risk of osteoporosis in women. The results of Prof Weaver and her research team's studies are being used to determine recommendations for calcium supplementation around the world.

South African specialists, including Dr Stanley Lipschitz, Prof Stephen Hough and Dr Aslam Amod will present various topics ranging from the importance of Vitamin D and Calcium supplementation in the treatment of Osteoporosis to an update on the latest treatment options in Osteoporosis.

Members of the medical fraternity and medical media are invited to attend these seminars. Prior booking is essential.

Drinks and food will be served following the lectures.
Application for CPD points has been submitted.

To book for any of the events please fax your details to Marieta Ferreira on 0865246965 or e-mail your details to mferreira@lantic.co.za. Please include your contact details.

Date	City	Venue
16 October 2007	Johannesburg	The Venue, Melrose Arch
17 October 2007	Cape Town	The Table Bay Hotel
18 October 2007	Durban	1on1 Events & Conference Centre, Gateway, Umhlanga

Time: 18h30 for 19h00