

Hansa Medical

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Results from a clinical multicenter trial with HBP-assay published in Critical Care Medicine

Results from a clinical multicenter trial with samples from Emergency Departments in Sweden, USA and Canada collected during 2011-2014 have been published online ahead of print by the scientific journal Critical Care Medicine. The study results show that the diagnostic method for assessing Heparin Binding Protein (HBP) predicts severe sepsis with significantly higher accuracy than other biomarkers available today. The study demonstrates that the HBP-assay has the potential to become a significant tool in helping predicting severe sepsis at emergency departments and infectious disease clinics. For open access to the publication, please visit:
http://journals.lww.com/ccmjournal/Abstract/publishahead/Heparin_Binding_Protein_Measurement_Improves_the.97183.aspx

"The results from the IMPRESSED study are promising and Axis-Shield is developing the HBP testing market globally and is working to attract major global IVD (In Vitro Diagnostics) players as potential sublicenses. In order to further strengthen the clinical validity of HBP-assay, Axis-Shield is currently coordinating additional clinical trials with HBP-assay in the US, Europe, China, South Korea and India. In addition, we are also developing alternative versions of the HBP-assay for improved routine clinical applicability." states Anil Vasishta, Managing Director, Axis-Shield Diagnostics

"The multicenter trial indicates that the HBP-assay has the potential to become a valuable tool for Emergency Departments and Infectious Disease clinics for prediction of severe sepsis.. Hundreds of thousands of lives can potentially be saved and costly intensive care may be cut through the prediction of severe sepsis and early treatment", states Göran Arvidson, CEO of Hansa Medical AB.

Background to the study

The HBP-assay is a novel diagnostic method developed and patented by Hansa Medical to help predict severe sepsis in patients with infectious disease symptoms. Hundreds of thousands of patients die every year due to severe sepsis as a complication to infections like urinary tract infection and pneumonia. These infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis although early prediction of risk patients is crucial for successful treatment. A seemingly stable infectious disease patient can within hours develop severe sepsis as manifested through clinical symptoms like organ failure and circulatory failure. Early prediction and treatment of risk patients is key to prevent death from severe sepsis.

Study results

The prospective clinical multicenter trial (IMPRESSED-study) involved 759 patients admitted to Emergency Departments in Sweden and the US with infectious disease symptoms. 674 patients were diagnosed with an infection, of whom 487 did not have organ dysfunction at enrollment. Of these 487 patients, 141 (29%) developed severe sepsis within 72 hours. 78% of these patients had elevated levels plasma-HBP prior to developing severe sepsis. HBP clearly outperformed those biomarkers available today for diagnosing or predicting severe sepsis including Procalcitonin, White blood cell count (WBC), CRP, Lactate. Procalcitonin was increased in 52.5% of the patients developing severe sepsis, WBC in 57.4%, CRP in 59.3%, and Lactate in 28.1%. Samples from a Canadian validation cohort of 104 patients confirmed the results of the Sweden/USA study. The diagnostic accuracy for HBP in predicting severe sepsis in the Canadian cohort was even higher than in the Sweden/US cohort. The sensitivity

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was 78% and the specificity was 95% in predicting severe sepsis among infected patients in the Canadian cohort.

Commercial development of HBP-assay

Hansa Medical and Axis-Shield Diagnostic Limited signed a collaborative agreement in 2009 for the commercialization of the HBP-assay. Axis-Shield is responsible for all clinical trials and further developments of the assay and Hansa Medical carries certain rights to royalties from Axis-Shield derived from sales of the HBP-assay as well as milestones payments and minimum royalties.

Need for better tools for prevention of severe sepsis

In the 2013 report “National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011” the US Department of Health and Human Services concludes that the most expensive condition treated in hospitals is sepsis, accounting for \$20.3 billion in annual costs for the U.S. healthcare system. Sepsis represented 5.2 % of the national costs for all hospitalizations in 2011, resulting in nearly 1.1 million discharges from U.S. hospitals. In a commentary to the report, The Sepsis Alliance concludes that sepsis alone causes 258,000 deaths annually in the US.

For further information, please contact:

Hansa Medical AB
Göran Arvidson, President and CEO
Mobile: +46 706-33 30 42
E-mail: goran.arvidson@hansamedical.com
www.hansamedical.com

About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes and diagnosis of severe inflammatory conditions. Its lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP, a market-launched diagnostic marker for severe sepsis, and EndoS, an antibody-modulating bacterial enzyme in pre-clinical development. The company is based in Lund, Sweden. Hansa Medical's share (HMED) is listed on Nasdaq First North in Stockholm with Remium Nordic AB as Certified Adviser.

The information in this press release is disclosed pursuant to the Securities Markets Act or the Financial Instruments Trading Act. The information was released for public disclosure on August 27, 2015 at 12.40 CET.