

PRESS RELEASE

EFFECTIVE PREVENTION OF CHRONIC GRAFT VERSUS HOST DISEASE BY ANTI-LYMPHOCYTE GLOBULIN AFTER STEM CELL TRANSPLANTATION

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Barcelona, Monday January 4, 2015 – A European Society for Blood and Marrow Transplantation (EBMT) labeled phase III clinical trial has found that the addition of anti-lymphocyte globulin (ATG) as part of the conditioning regimen in patients with Acute Leukaemia who underwent allogeneic stem cell transplantation from their HLA-identical sibling led to a significant reduction of chronic graft-versus host disease (cGvHD) after transplantation without increase of relapse and infectious complications. These results are published in *The New England Journal of Medicine (NEJM)* on January 7, 2016.

Allogeneic stem cell transplantation from HLA-identical sibling is a curative and established treatment approach for patients with haematological malignancies such as leukaemia. Chronic graft-versus-host disease (GvHD) is a major complication after allogeneic stem cell transplantation and results in late morbidity and mortality as well as in reduction of quality of life. Most of the randomized studies aiming to reduce the incidence of chronic GvHD failed and those who showed some benefit by depleting immunocompetent T-cells from the graft resulted in a higher risk of leukemia relapse.

In the presented study, the researchers randomly assigned 161 patients with acute leukaemia in a 1:1 ratio to receive ATG or no ATG as part of the conditioning regimen prior to allogeneic stem cell transplantation. Anti-lymphocyte globulin (ATG-Fresenius®) derived from rabbits after immunization with cells from a human T-cell line. The highly purified immunoglobulin consists of antibodies exhibiting a direct effect to T-cells, but also against antigen presenting cells such as B-Cells and dendritic cells. The addition of ATG to the conditioning regimen led to a highly significant reduction of especially severe chronic graft-versus host disease without influencing negatively the relapse rate, infectious complications and overall survival. Furthermore, the addition of ATG resulted in an improved chronic GvHD and relapse-free survival.

The principal investigator of the trial, Nicolaus Kröger, Medical Director of the Department of Stem Cell Transplantation at the University Hospital Hamburg, Germany and Chair of the EBMT Chronic Malignancies Working Group explains: “The results of our multicenter study significantly improved the outcome of leukemia patients receiving an allogeneic stem cell transplant from their HLA-identical sibling by reducing the risk of chronic GvHD without obvious risk of relapse, which improves the quality of life for our patients after the transplant and will change our daily practice.”

This achievement was only possible by a European collaborative effort from many transplant centers and physicians in Germany, Italy (coordinated by Dr Francesca Bonifazi, S. Orsola-Malpighi Hospital - Institute of Hematology and Medical Oncology, Bologna University) and Spain (coordinated by Dr Carlos Solano, Hospital Clinico Valencia, Spain).



The authors of this important contribution in the field of allogeneic stem cell transplantation received the prestigious van Bekkum Award at the 41st Annual Meeting of the European Society for Blood and Marrow Transplantation in Istanbul.

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About the European society for Blood and Marrow Transplantation (EBMT)

The EBMT is a not-for-profit medical and scientific organisation established in 1974. It is dedicated to fighting life-threatening blood cancers and diseases and improving patients' lives. The EBMT Members - more than 4,000 physicians, nurses, scientists and other healthcare professionals - participate in a unique collaborative network of peers involved in haematopoietic stem cell transplantation (HSCT) and cellular therapy research. The membership encompasses at least 600 centres who are performing or are involved in HSCT in more than 60 countries. The EBMT holds a central role in performing co-operative studies and disseminating state-of-the-art knowledge aimed at increasing survival rates and enhancing the quality of life of patients with life-threatening blood cancers and diseases.

For further information about the EBMT, please visit the website: www.ebmt.org and follow us on Twitter: @TheEBMT