



PRESS RELEASE

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Results of an EBMT phase III randomized trial on dose-reduced versus standard conditioning followed by allogeneic stem cell transplantation for patients with myelodysplastic syndrome

Barcelona, 4th May 2017 – The European Society for Blood and Marrow Transplantation announces the results from the RICMAC trial, published in the *Journal of Clinical Oncology* on Tuesday on the 2nd of May of 2017. These results show evidence that reduced-intensity conditioning regimen (RIC) result in at least a 2-year relapse-free survival and overall survival similar to standard conditioning regimen (MAC) in patients with Myelodysplastic Syndrome (MDS) or secondary acute myeloid leukemia (AML).

RICMAC is an international, multi-centre, investigator-based, open-label, randomized phase III trial that involved 18 transplant units in seven countries between May 2004 and December 2012. A total of 129 patients aged 18-65 years were enrolled. In this trial reduced-intensity conditioning (busulfan-based RIC) is compared to standard myeloablative conditioning regimen (MAC) followed by allogeneic stem cell transplantation from related or unrelated donors in patients with MDS or secondary AML.

Myelodysplastic syndromes (MDS) are a heterogeneous group of clonal hematopoietic disorders that are characterised by abnormal cellular maturation that results in cytopenias and variable risk of progression to acute leukemia. It was to address the needs of patients suffering from MDS that the RICMAC trial was set up.

Conditioning is the very high dose chemotherapy treatment that is given in the days before the stem cell transplant. Reducing the intensity of the conditioning regimen may lead to less toxic effects in patients, but there is concern about a higher risk of relapse.

The results of the trial show that engraftment was comparable between both groups. The cumulative incidence of non-relapse mortality after 1 year was 17% after RIC and 25% after MAC. The incidence of relapse at 2 years was 17% after RIC and 15% after MAC, which resulted in a 2-year relapse-free survival and overall survival of 62% and 76% after RIC, and 58% and 63%, respectively, after MAC.

Trial Principal Chief Investigator Professor Nicolaus Kröger from University Hospital Eppendorf in Hamburg, Germany, said “our study shed new lights on expected benefits of reduced-intensity conditioning regimen that can be offered as a curative treatment approach especially in older patients with MDS”.

This trial was supported in part by a grant from Pierre Fabre
Clinical trial information: NCT01203228
See online publication: <http://ascopubs.org/doi/full/10.1200/JCO.2016.70.7349>

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 500 centres who are performing or are involved in HSCT in more than 50 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

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