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# EBMT Study Provides 10-Year Evidence on Autologous HCT in Severe Systemic Sclerosis

**An international study reports 60% progression-free survival at 10 years after autologous bone marrow transplantation, adding important evidence on sustained positive clinical outcomes and long-term safety in patients treated for early severe systemic sclerosis.**

Systemic sclerosis is a rare chronic and heterogenous autoimmune disease characterised by progressive fibrosis of the skin and internal organs, with severe forms associated with high morbidity and mortality. Autologous haematology cell transplantation (HCT) is an established treatment option (grade A level of evidence) for carefully selected patients with early diffuse severe disease, supported by randomised clinical trials. However, very long-term evidence on outcomes approaching a decade has remained limited.

The NISSC1-LTE study conducted by the Autoimmune Diseases Working Party of EBMT is the first international prospective providing long-term results on autologous HCT in patients with early severe systemic sclerosis. Published in *The Lancet Rheumatology*, the study followed 80 patients for a median of 9.2 years after transplantation.

NISSC1-LTE extends the original prospective EBMT NISSC1 study, drawing on follow-up data from 13 participating centres in France, Germany, the Netherlands, Italy, Spain, Switzerland and Brazil.

**Long-Term Outcomes in Severe Systemic Sclerosis**

The EBMT- NISSC1 cohort comprised patients who underwent their first autologous HCT for severe progressive systemic sclerosis between 2012 and 2016. The findings provide evidence on sustained disease control and the long-term risks of treatment.
At 10 years, estimated progression-free survival was 60% (95% CI 47–71) and overall survival was 71% (56–82). In addition, 34 of 80 patients (43%) were alive and had not required further immunosuppressive treatment at their last follow-up.
The median modified Rodnan skin score, a measure of skin involvement, decreased from 24 at baseline to 6 at five years and 5 at 10 years. Median forced vital capacity was 72% of predicted at baseline and 71% at 10 years, while median diffusing capacity of the lungs for carbon monoxide (DLCO) was 59% and 61% of predicted, respectively.

*“These long-term findings help clinicians understand the durability of systemic sclerosis disease control following autologous HCT, while highlighting the risks that require continued monitoring. They also*

*reflect years of collaboration among investigators, clinical teams including haematologist, rheumatologists and data specialists in expert centres from Europe to Brazil across the EBMT Autoimmune Diseases Working Party network."* said **Joerg Henes** (Germany, University Hospital Tübingen) and **Dominique Farge** (Paris, St-Louis Hospital), study's lead authors.

**Long-Term Safety and Continued Follow-Up**

The study also assessed mortality and late complications. Eighteen patients died during follow-up: five early deaths (6% of the cohort) were attributed to HCT, nine to disease progression, two to post-HCT malignancies and two to late serious infections. Estimated non-relapse mortality at 10 years was 13% (95% CI 6–24).These findings underline the importance of careful patient selection, specialist pre-transplant assessment and structured long-term monitoring in experienced centres.
As an observational study without a control group, NISSC1-LTE does not directly compare HCT with alternative treatments. Some longitudinal data were incomplete, and 12 patients were lost to follow-up.

**International Collaboration Across EBMT Centres**

Led by Pr Joerg Henes (MD, PhD Germany) and Pr Dominique Farge (MD, PhD, France) on behalf of the Autoimmune Diseases Working Party of EBMT, NISSC1-LTE reflects sustained collaboration between transplant physicians, rheumatologists, multidisciplinary clinical teams and data specialists from EBMT. Patient representatives also helped shape the research question and study conduct.

Results from NISSC1-LTE were previously presented at the 2026 Annual Meeting of EBMT. The findings support consideration of autologous HCT in carefully selected patients with severe systemic sclerosis, in line with existing EBMT, EULAR and CIBMTR recommendations, and offer a long-term reference for evaluating emerging cellular therapies. The study illustrates the contribution of EBMT Working Party research and shared clinical data to evidence-informed care.

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## About EBMT

**A global healthcare society enabling better patient care through advanced therapies.**

EBMT is a non-profit society dedicated to improving patient outcomes through haematopoietic cell transplantation and cellular and gene therapies. By bringing together healthcare professionals, researchers and institutions worldwide, EBMT advances research, education, quality standards and collaboration across the field.

The Autoimmune Diseases Working Party (ADWP) is EBMT's leading international network for severe autoimmune diseases, driving research, registry-based evidence generation and clinical innovation to improve patient care and inform best practice globally.

Visit our website at www.ebmt.org and connect with our online community.

## Media Contact

**Mélanie Chaboissier**
Communication Coordinator, EBMT
Email: melanie.chaboissier@ebmt.org