





Graft-versus-host disease prophylaxis in unrelated donor transplantation

# A randomized clinical trial comparing two global standards

To address a major evidence gap in the field of Graft-versus-host disease (GvHD) prophylaxis, a randomized trial was initiated to directly compare post-transplant cyclophosphamide (PTCy) and anti-thymocyte globulin (ATG) in the setting of unrelated donor peripheral blood stem cell transplantation. While PTCy has shown promise in haploidentical hematopoietic stem cell transplantation by mitigating the effects of HLA mismatch and reducing GvHD, its role in unrelated donor transplantation remains unclear.

Current practice in Europe relies predominantly on ATG, but both prophylactic strategies carry significant risks of GvHD and relapse. Our study is designed to offer high-level evidence on whether PTCy can provide superior immune reconstitution, better GvHD control and improved survival outcomes in the unrelated donor context.

The recruitment of patients is already completed, the follow-up of patients is currently ongoing and first results are to be expected at the end of 2025.



ClinicalTrials ID: NCT05153226



1. Patient in need of stem cell transplantation



2. Transplantation including GvHD prophylaxis therapy with either ATG or PTCy



3. Outcome documentation with focus on GvHD

#### Largest GvHD prophylaxis study worldwide

Comparison of two therapeutic approaches for GvHD prophylaxis in the context of stem cell transplantation

Powerful network of German transplantation centers enabled faster recruitment than planned

# Together, we revolutionize blood cancer treatment

The Clinical Trials Unit (CTU) is the scientific research department of DKMS, contributing to advancements in the diagnosis and treatment of blood cancer and hemoglobinopathies. We are known for our comprehensive range of specialized services and commitment to innovation. Bringing together a team of experts with extensive experience in clinical research, quality management, IT, statistics, data management, immunology, and regulatory affairs, the department approaches each project with a well-rounded perspective, effectively addressing complex challenges.

DKMS' Clinical Trials Unit conducts research aiming directly at improving the treatment of blood cancer and of patients in need of cell therapy.

## **Our tasks**

#### Performing our own research



Clinical trials



Laboratory & immunology research



Research studies using resources of the Collaborative Biobank



Donor registry sciences

### Supporting external research



Collaborative Biobank (CoBi)



National research data infrastructure for research data in Germany



John Hansen Research Grant



External study requests

# Creating resources for future research through a collaborative approach

Our collaborative biobank (CoBi) collects **blood samples from interested participants** (donors and patients), prepares them biologically and **stores them under standardized laboratory conditions**. In addition, medical and sample-related **data of the participants are stored in encrypted form** in the CoBi database.

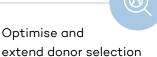
The collection and storage of blood samples and data is carried out within a framework of use defined jointly by all cooperation partners. The samples and data may only be used to:



Improve the prevention, diagnosis and treatment of blood cancers



projects aimed at improving the outcome of transplantations



for allogeneic stem cell transplantations



For more information, see our publication:

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# **DKMS**

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- Covers a variety of substantial tasks to support and conduct medical research
- Combines critical know-how of experts needed for clinical trials
- Provides data & analysis for strategic decision making

#### **More information**



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