

Multi-Center Superiority Clinical Trial, Supported by Terumo Blood and Cell Technologies, Aims to Significantly Reduce Complications From Acute Chest Syndrome in Adult Sickle Cell Disease Patients

- *Acute chest syndrome (ACS) is a severe complication of sickle cell disease (SCD) and the leading cause of hospitalization and death among adult patients with SCD¹*
- *Researchers at Henri Mondor University Hospital in France will evaluate the efficacy and safety of early goal-directed automated red blood cell exchange versus manual exchange to accelerate the resolution of severe ACS in adult patients with SCD*
- *Currently, no standard treatment exists to halt ACS*
- *The ARCAD clinical trial aims to establish high-level evidence for recommendations for the management of severe ACS*

Lakewood, CO – December 3 2024 – Terumo Blood and Cell Technologies (Terumo BCT), a medical technology company, announced funding support for a new clinical trial. Led by sickle cell disease (SCD) experts at France’s Henri Mondor University Hospital and sponsored by Assistance Publique-Hôpitaux de Paris, the ARCAD trial aims to confirm that the benefits from early treatment of severe acute chest syndrome (ACS) using automated red blood cell exchange versus manual exchange will translate to a faster resolution of ACS and reduced adverse events during hospitalization for these extremely vulnerable patients. Speeding ACS treatment could have significant potential benefits of reducing morbidity and mortality in adult patients with SCD and reduced costs for hospital stays. Importantly, this could help make automated red blood cell exchange part of the standard of care for severe ACS in France and around the world.

SCD is a genetic blood disorder that causes misshapen red blood cells to get stuck in the blood vessels, leading to severe pain episodes from vaso-occlusions and other serious complications. ACS occurs when vaso-occlusion occurs within the pulmonary vasculature. It can progress quickly and requires prompt treatment. Management of ACS mostly involves a symptomatic approach using hydration, analgesics, supplemental oxygen, and red blood cell exchange.^{2,3} Red blood cell exchange, which replaces damaged cells with healthy ones, helps improve oxygenation and can be done using manual or automated exchange. Manual exchange requires time-consuming sequential steps, while automated red blood cell exchange meets hematological targets more quickly and consistently.

The study will be led by Dr. Armand Mekontso Dessap, head of the Medical Intensive Care Unit at Henri Mondor and an intensivist focused on ACS. “It is a frightening complication for patients and their families, who not only watch a loved one suffer, but then worry they may share the awful experience in the future. We urgently need standardized protocols and tools to treat ACS. Current methods rely on old techniques,” said Dr. Mekontso Dessap. “There hasn’t been enough research to inform best practices and high-level recommendations. We hope this study will pave the way for standardized treatment for health systems in France and around the world.”

“At Terumo BCT, we are deeply committed to advancing care for sickle cell disease,” said Koenraad Dierick, Vice President Patient Access, Terumo BCT. “Supporting the research of Dr. Mekontso Dessap and his team at Henri Mondor, who likely treat more SCD patients in their ICU than any other hospital in Europe, is a key part of our mission to expand access to this treatment and ensure that more patients benefit from automated red blood cell exchange.”

Notes for Editors:

- ARCAD is an abbreviation for Early Goal-directed Automated Red Blood Cell Exchange for Acute Chest Syndrome in Sickle Cell Disease: A Multicenter, Randomized, Clinical Trial.
- France has the highest prevalence of SCD patients in Europe, estimated at 30,000.⁴

[1] Vichinsky E.P, Neumayr L.D et al Causes and outcomes of the acute chest syndrome in sickle cell disease. *N Engl J Med.* 2000;342:1855-1865 doi: 10.1056/NEJM200006223422502

[2] Jain S, Bakshi N, Krishnamurti L. Acute chest syndrome in children with sickle cell disease. *Pediatr Allergy Immunol Pulmonol.* 2017;30(4):191-201. doi:10.1089/ped.2017.0814

[3] Piel FB, Steinberg MH, Rees DC. Sickle cell disease. *N Engl J Med.* 2017;377(3):305. doi: 10.1056/NEJMra1510865

[4] Leleu H, Arlet JB, Habibi A, et al. Epidemiology and disease burden of sickle cell disease in France: A descriptive study based on a French nationwide claim database. *PLoS One*. 2021;16(7):e0253986. doi: 10.1371/journal.pone.0253986

About Terumo Blood and Cell Technologies

Terumo Blood and Cell Technologies (Terumo BCT) is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees worldwide believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

Terumo BCT's customers include blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers and private medical practices. Our customers are based in over 160 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, along with five regional headquarters, seven manufacturing sites and six innovation and development centers across the globe. Terumo Blood and Cell Technologies is a subsidiary of Terumo Corporation (TSE: 4543), a global leader in medical technology.

Spectra Optia™ Apheresis System

The Spectra Optia system is a user-friendly, versatile, industry-leading therapeutic apheresis, cell processing and cell collection platform that allows operators to spend more time focusing on patient care.

Therapeutic apheresis is used widely for a variety of applications. For example, practitioners use red blood cell exchange (RBCX) for sickle cell disease treatment; cell collections for stem cell transplantations and to collect starting material for cell therapies; and therapeutic plasma exchange (TPE) to treat many diseases in both the chronic and acute setting in the neurology, nephrology and hematology spaces.

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