CTC Clinical Research Core

Under the leadership of Amna Daud, MD MPH, the Clinical Research Core provides nursing and administrative support to clinicians in executing a diverse portfolio of clinical trials related to transplantation. The core specializes in: Biomarker Development Studies; Transplant Surgical Trials; Living Donor Trials (Kidney and Liver), Pharmaceutical Drug Trials (Phase II-IV); Cellular Therapy (including stem cell and islet cell transplants) and Transplant Infectious Diseases Trials. The current portfolio includes about 75 studies with funding from Federal (54%), Industry Sponsored (32%) and other (14%) agencies.

Highlighted Projects:

A randomized, controlled, multi-center, safety and efficacy study of FCR001 cell-based therapy relative to a tacrolimus and mycophenolate-based regimen in de novo living donor renal transplant recipients, and safety in FCR001 donors- TALARIS FREEDOM-1 Pt: Leventhal

The purpose of this study is to assess the safety, efficacy and overall benefit of FCR001 cell therapy in de novo living donor renal transplantation, relative to a standard-of-care control regimen including tacrolimus, mycophenolate, antibody induction, and corticosteroids. FCR001 is a novel, cryopreserved allogeneic somatic cell therapy, and derived from mobilized peripheral blood mononuclear cells from the same donor as the allograft, and containing hematopoietic progenitor cells, facilitating cells and αβ T cells. The rationale is to establish durable chimerism and donor-specific tolerance in the recipient enabling freedom from chronic immunosuppression and its associated toxicities.

A Phase 4, Multi-Center, Open-Label Study of Mavyret (Glecaprevir/Pibrentasvir) to Treat Recipients of Transplanted Kidneys from Deceased Donors with Hepatitis C Virus (MYTHIC: MavYret for Transplanting kidneys with Hepatitis C)- Pt: Friedewald

Approximately 500 kidneys from HCV-infected donors are discarded annually in the United States. Strategies to increase utilization of HCV-infected kidneys to shorten wait time for patients on dialysis are desperately needed. The purpose of this study is to determine if Glecaprevir, Pibrentasvir (G/P) treatment when initiated early after kidney transplant (e.g., as early as 3 days post-transplant) can prevent significant HCV viremia and prevent establishment of HCV infection in the liver and associated complications.

A Prospective Randomized Multi-Center Study of the Use of the LifePort® Liver Transporter (LLT) System with Vasosol® as Compared to Static Cold Storage in Orthotopic Liver Transplants (PILOT)-Pt: Borja-Cacho

The purpose of this study is to provide reasonable assurance of the safe and effective use of the LLT System with Vasosol® for the preservation of whole explanted livers, thereby confirming the findings of previous clinical studies conducted using a prototype of the LLT System with Vasosol®.

To discuss conducting a transplant related clinical trial using the staff of the clinical research core, please contact: a-daud@northwestern.edu.