

BISC/ImmPort Data Release 1 studies

March 21, 2013

Study Program: CCTPT

Title: Pediatric Kidney Transplant without Calcineurin Inhibitors (CN01), 5U01AI067075-03

Accession: SDY131

Subjects: 34

Study PI, contact: William Harmon, Children's Hospital of Boston, Division of Nephrology, Boston, MA

Study Description: Unique issues facing pediatric transplant patients include the need for growth and significant side effects of immunosuppressive therapy such as nephrotoxicity, hepatotoxicity and cosmetic issues. This study evaluates the use of Sirolimus, a TOR-inhibitor, in place of calcineurin inhibitors for post-transplant Immunosuppression in pediatric living-donor kidney transplant recipients. Treatments also include Dacluzimab, a humanized anti-CD25 monoclonal antibody, mycophenolate mofetil (MMF) and a steroid taper, all targeting issues unique to these transplant recipients.

Assays in ImmPort: Q-PCR

Clinical Assessments in ImmPort: 23

Study Program: CCTPT

Title: Tacrolimus with Steroids and Standard Daclizumab versus Steroid-Free Tacrolimus with Extended Daclizumab in Pediatric Renal Transplantation (SNS01), 5U01AI067075-03

Accession: SDY132

Subjects: 130

Study PI, contact: Oscar Salvatierra, Lucile Salter Packard Children's Hospital, Palo Alto, CA

Study Description: The purpose of this study is to determine the safety and effectiveness of a corticosteroid-free treatment regimen for children and adolescents who have received kidney transplants. This is a randomized (1:1), open-label, parallel group design study. Arm 1 is traditional steroid-based immunosuppression treatment and arm 2 is steroid-free immunosuppression treatment with prolonged daclizumab induction.

Assays in ImmPort: Q-PCR

Clinical Assessments in ImmPort: 40

Study Program: CCTPT

Title: Steroid Withdrawal in Pediatric Kidney Transplant Recipients (SW01), 5U01AI067075-03

Accession: SDY133

Subjects: 273

Study PI, contact: William Harmon, Children's Hospital of Boston, Division of Nephrology, Boston, MA

Study Description: One side effect of steroid maintenance therapy for pediatric renal transplant recipients is growth retardation. The purpose of this study is to examine the effects of withdrawing steroids on graft rejection and growth rate. This is a randomized 1:1 study where arm 1 treatment involves steroid withdrawal and arm 2 is low dose steroid treatment.

Assays in ImmPort: none

Clinical Assessments in ImmPort: 29

Study Program: CCTPT

Title: Safety in Immunomodulatory Functions of Campath-1H (PC01), 5U01AI067075-03

Accession: SDY134

Subjects: 35

Study PI, contact: William Harmon, Children's Hospital of Boston, Division of Nephrology, Boston, MA

Study Description: this is a multi-center, open label, single arm trial to evaluate the safety of alemtuzumab after kidney transplantation as part of a multi-therapy regimen to prevent kidney graft loss and death and to avoid steroids and chronic use of calcineurin inhibitors in pediatric renal transplant recipients

Assays in ImmPort: Q-PCR

Clinical Assessments in ImmPort: 31

Study Program: Modeling Immunity to Enteric Pathogens (MIEP), HHSN272201000056C

Title: CDIFF-PO1,

Accession: SDY100

Subjects: 113

Study PI, contact: Moncia Viladomiu, Virginia Bioinformatics Institute, Blacksburg, VA

Study Description: This study intends to characterize the role of peroxisome proliferator-activated receptor (PPAR) gamma in *Clostridium difficile*-associated disease (CDAD), immunity and gut pathology using a mouse model of *C. difficile* infection in wild-type and T cell-specific PPAR gamma null mice. Treatment arms include *C. difficile* infected, Control and unknown.

Assays in ImmPort: RT-PCR, Flow cytometry

Clinical Assessments in ImmPort: none

Study Program: Immune Tolerance Network

Title: RAVE—Rituximab for the Treatment of Wegener’s Granulomatosis and Microscopic Polyangiitis

Accession: SDY91

Subjects: 197

Study PI, contact: Ulrich Specks, Mayo Clinic College of Medicine, Rochester, MN,
John H. Stone, Massachusetts General Hospital, Boston, MA

Study Description: Antineutrophil cytoplasmic antibodies (ANCA)-associated Vasculitis is the most common type of small blood vessel inflammation in adults. ANCA-associated Vasculitis includes Wegener’s granulomatosis (WG) and microscopic polyangiitis (MPA). Rituximab is used to treat certain types of cancer and is being evaluated in this study as a treatment for WG and MPA.

Assays in ImmPort: Flow cytometry, ELISA

Clinical Assessments in ImmPort: 21

Study Program/Contract: Immune Response to Virus Infection during Pregnancy (VIP-003, NO1-AI-50025)

Title: Immune Response of Patients during Pregnancy

Accession: SDY36

Subjects: 58

Study PI, contact: Thomas Moran, Mt. Sinai Hospital, New York, NY.

Study Description: This study characterizes the changes in immune response of healthy women during pregnancy and lactation. By challenging patient cells with chimeric NDV viruses the study investigates immune agonists from category A-C pathogens to determine whether pregnancy changes immune response which could lead to profound pathogen specific immunodeficiency.

Assays in ImmPort: ELISA, flow cytometry, qPCR

Clinical Assessments in ImmPort: 26

Study Program/Contract: Immune Response to Virus Infection during Pregnancy (VIP-004), NO1-AI-50025

Title: Vaccination Cohort
Accession: SDY37
Subjects: 335

Study PI, contact: Thomas Moran, Mt. Sinai Hospital, New York, NY.
Study Description: This study intends to characterize changes in the immune response that occur during pregnancy. Healthy pregnant women, receiving the H1N1 influenza vaccine any time during pregnancy, are assessed for variances in antibody titer across trimesters and post-partum, occurrences of influenza-like illnesses among the study patients and their household members and the occurrence of influenza-related upper respiratory illness.
Assays in ImmPort: ELISA, virus neutralization
Clinical Assessments in ImmPort:

Study Program/Contract: Protective Immunity in Transplant Recipients
Title: Impact of Immunosuppression regimens on protective immunity in renal transplant recipients, NO1-AI-50025
Accession: SDY33
Subjects: 116
Study PI, contact: Christian Larsen, Emory University, Atlanta, GA
Study Description: A prospective longitudinal study comparing renal transplant patients with controls to determine the biological mechanisms that underlie the immunosuppressed state associated with immunosuppressive regimens after transplantation. 7 arms using either Tacrolimus maintenance, Sirolimus maintenance, or Efalizumab with or without induction, donor controls, healthy controls.
Assays in ImmPort: Flow cytometry, HLA typing, ELISPOT
Clinical Assessments in ImmPort: none

Study Program/Contract: Protective Immunity in Transplant Recipients
Title: Comparison of immune response to influenza vaccine in transplant patients and health controls, NO1-AI-50025
Accession: SDY34
Subjects: 97
Study PI, contact: Christian Larsen, Emory University, Atlanta, GA
Study Description: Prospective longitudinal study to determine the effects of chronic immunosuppressive therapies on the magnitude and character of the adaptive immune response to influenza vaccination in healthy controls compared to renal transplant patients. Two arms in this study: arm 1 6 month post-transplant patients receiving trivalent influenza vaccine, arm 2 Healthy controls
Assays in ImmPort: Flow cytometry, genotyping
Clinical Assessments in ImmPort: none

Study Program/Contract: Protective Immunity in Transplant Recipients
Title: Responses to and control of vaccinia in immunosuppressed Rhesus Macaques
Accession: SDY35
Subjects: 19
Study PI, contact: Christian Larsen, Emory University, Atlanta, GA
Study Description: A detailed mechanistic study of the immune response to vaccinia vaccine in immunosuppressed Rhesus macaques and development of a relevant preclinical model in which the

efficacy and safety of vaccines in the setting of transplantation can be evaluated. Five arms testing vaccine response with/without immunosuppressant drugs.

Assays in ImmPort: microarray, flow cytometry, ELISA

Clinical Assessments in ImmPort: none