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NUTORC

**Northwestern University
Transplant Outcomes
Research Collaborative**

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Quality of Life
Risk Predictors & Economics
Informed Consent &
Disparities
Access & Allocation
Health Literacy & Medication
Adherence
Aging

Cores

Health Informatics
Biostatistics
Administrative
Education

Administrative Core

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*NUTORC is part of the
Comprehensive Transplant
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Learn more about NUTORC at:

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August 2016

Transplant Infectious Diseases

Norovirus is one of the most common causes of gastroenteritis in the United States. While it represents a syndrome of nausea, vomiting and diarrhea that typically resolves in 2-3 days in otherwise healthy individuals, it can cause prolonged and often intermittent episodes of diarrhea among transplant recipients. The Transplant Infectious Diseases group at Northwestern University's Comprehensive Transplant Center has recently documented that symptomatic infection can persist for years and result in gradual renal dysfunction in transplant recipients. Despite its significant impact in this population, there are no proven treatments for norovirus in transplant recipients. Dr. Michael Ison, a member of NUTORC, recently secured a 6.5 million dollar contract from NIAID to better understand the natural history of norovirus in transplant patients and to assess the safety and efficacy of nitazoxanide for the treatment of norovirus in hematopoietic stem cell and solid organ transplant patients.

The study will be conducted at 10 transplant centers throughout the United States (Cincinnati Children's Hospital Medical Center, Johns Hopkins University, University of Alabama at Birmingham, University of Kansas, University of Michigan, University of Nebraska, University of North Carolina at Chapel Hill, University of Pittsburgh, and the University of Washington, in addition to Northwestern University). In the study, which will take place over the next 5 years, a total of 160 subjects ≥ 12 years of age with norovirus will be enrolled in a randomized control trial studying two treatment groups: active nitazoxanide and placebo. Randomization will be stratified by age group (pediatric (12-18 years) vs. adult > 18 years), chronicity of norovirus-associated symptoms (acute (<14 days) vs. chronic (≥ 14 days)) and transplant type (solid organ (SOT) vs. hematopoietic stem cell transplant (HSCT)). Enrolled subjects will participate in 2 phases of the study: Treatment Phase, which will include dosing with the assigned study agent for 28 days and study visits on study day 1, 7 ± 4 days, 14 ± 4 days, 21 ± 4 days, and 28 ± 4 days; Longitudinal Monitoring Phase which will include study visits on study day 60 ± 14 days, 120 ± 14 days and 180 ± 14 days. All laboratory assessments will be performed by colleagues at Cincinnati Children's Hospital Medical Center.

This unique collaboration will inform the optimal approach to the management of norovirus in transplant patients. More importantly, this team will continue to collaborate to apply for other grants placing NUTORC at the center of cutting edge, federally-funded Transplant Infectious Diseases research.

The study leverages the various expertise of the Northwestern University Comprehensive Transplant Center and NUTORC. Specifically, the leadership will be driven by the NU Transplant Infectious Diseases group, the statistics will be run through the NUTORC be run through the NUTORC Administrative Core and NUCTC Grants Management Core.



Michael G. Ison. MD MS FIDSA FAST

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