

Cell therapy may slow kidney damage from type 2 diabetes

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University of Galway, in collaboration with the NEPHSTROM Consortium, has announced promising results from a new cell therapy trial for people living with diabetes.

The NEPHSTROM clinical trial is taking the first steps to investigate the value of a novel cell therapy for adults who have type 2 diabetes and worsening [kidney](#) disease, despite best medical treatment.

Results from the NEPHSTROM clinical trial were presented in November at the American Society of Nephrology's Kidney Week meeting in Orlando, Florida. It showed that a single dose of ORBCEL-M, given intravenously to carefully selected adults with worsening kidney disease due to diabetes was safe and associated with better preservation of kidney function compared to a placebo. Patients taking part in the trial were followed closely for 18 months after receiving ORBCEL-M.

The ORBCEL-M cell therapy is a mesenchymal stromal cell (MSC) preparation manufactured from healthy bone marrow which was discovered and developed in Galway by Orbsen Therapeutics Ltd, a spinout company from University of Galway.

The clinical trial is being led from the Mario Negri Institute for Pharmacological Research IRCCS in Bergamo, Italy and carried out jointly at leading medical centers in Galway, Bergamo, Birmingham and Belfast.

Trial investigator, Professor Matt Griffin, a senior researcher at University of Galway's Regenerative Medicine Institute (REMEDI) and a Consultant Nephrologist at Galway University Hospitals said, "Nearly a quarter of a million people in Ireland are living with diabetes and we know that more than 40% of them have evidence of kidney disease—often referred to as diabetic kidney disease or DKD for short.

"In type 2 diabetes, as many as one third of those with DKD have worsening kidney function despite the best medical therapy we can offer. These people are at high risk for requiring dialysis or kidney

transplantation in the years ahead—both of which are complex treatments with potentially serious complications."

"In NEPHSTROM, our goal is to secure evidence that a cell therapy, such as ORBCEL-M, is safe and can slow the course of DKD to help more people with diabetes avoid the need for dialysis or transplantation. It was exciting to report that our first analysis of results from the trial supports that goal."

Dr. Steve Elliman, who discovered the ORBCEL-M therapy, is Chief Scientific Officer for Orbsen Therapeutics. Dr. Elliman said, "At Orbsen Therapeutics we are motivated by improving [patient care](#). Diabetic patients with progressive [kidney disease](#) eventually require dialysis and often a kidney transplant. While dialysis improves the quality of life of patients with kidney failure, it is expensive and does not prevent further decline of kidney function."

"Additionally, dialysis takes four hours per session and three times a week—creating logistic and economic challenges for the patient. Our goal with ORBCEL-M is to resolve systemic inflammation and improve kidney function, so that patients will not require dialysis or a kidney transplant. We're encouraged by the safety profile and the preliminary efficacy signals in patients with DKD reported by the NEPHSTROM trial. We look forward to continued collaboration with our University of Galway and NEPHSTROM partners to advance this new medicine through Phase 3 efficacy trials and a market approval."

Dr. Veronica McInerney, Administrative Director at the HRB Clinical Research Facility at University of Galway said, "Without patient involvement in [clinical trials](#), advances in new treatments are simply not possible. We are fortunate to have the HRB Clinical Research Facility Galway, a clinically equipped space to see and treat patients on trials. We are hopeful that [future generations](#) will benefit from the willingness

of patients to participate in trials, such as the NEPHSTROM trial."

Professor Timothy O'Brien, Director of the Regenerative Medicine Institute (REMEDI), at the University of Galway and Consultant Physician in Endocrinology at Galway University Hospitals and the overall lead of the NEPHSTROM project, said, "University of Galway's ecosystem is set up to facilitate and lead international trials of this nature. The Cell Therapy GMP manufacturing facilities at the Centre for Cell Manufacturing Ireland, located in the University, along with the HRB Clinical Research Facility, the close partnership with Saolta University Health Care Group and REMEDI have been instrumental in making the progression of this potential new therapy possible."

More information: Conference:

www.asn-online.org/education/kidneyweek/

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