Biomarker-guided immunosuppression following kidney transplantation successfully tested

International study coordinated by MedUni Vienna demonstrates safety of a new approach to more personalised dosing of immunosuppressive drugs

(Vienna, 08 June 2026) An international research team coordinated by the Medical University of Vienna has demonstrated in a clinical trial that Torque-Teno-virus-guided dosing of immunosuppressants in kidney transplant recipients is safe. The results of the TTVguideIT study, recently being presented at the annual congress of the European Society of Nephrology, suggest that immunosuppressive therapy could be further personalised and reduced in certain patient groups in the future. The study forms the central conclusion of the EU project TTVguideTX, which was coordinated by Gregor Bond from the Division of Nephrology and Dialysis at the Department of Medicine III at MedUni Vienna.

Following a kidney transplant, patients must take medication that suppresses the immune system on a long-term basis. This immunosuppression protects the transplanted organ from rejection. However, if it is too strong, the risk of infection increases; if it is too weak, it can lead to damage to or loss of the organ. To date, dosing has usually been controlled based on fixed target drug levels in the blood. However, these values provide only limited insight into how strongly an individual's immune system is actually suppressed.

The TTVguideIT study investigated whether the Torque-Teno virus, or TTV for short, could serve as a biomarker to help manage immunosuppression more individually. TTV is present in many people, does not cause disease, and allows conclusions to be drawn about the activity of the immune system: low TTV levels may indicate an overactive immune system, whilst high levels may indicate an underactive immune system.

"Our aim was to adjust immunosuppression not only according to fixed drug levels, but to align it more closely with the patients' actual immunological status," says Gregor Bond, overall coordinator of the project. "The study shows that TTV-guided adjustment of the dose of the immunosuppressive drug tacrolimus was safely possible in the patient group studied."

260 patients across 13 European centres

The randomised, controlled Phase II study included 260 adult, stable kidney transplant recipients with low immunological and infectious disease risk. The study was conducted at 13 academic centres in Austria, Germany, France, the Czech Republic, the Netherlands and Spain. Four months after transplantation, patients were randomised to either TTV-guided tacrolimus dosing or standard treatment.

The primary endpoint comprised infections, graft rejection, graft loss or death. In the TTV-guided group, this composite endpoint occurred in 35 per cent of patients, compared with 38 per cent in the control group. The study thus achieved its objective of demonstrating the non-inferiority of TTV-guided dosing compared with standard treatment. The rejection rates in the protocol biopsies after twelve months were comparable in both groups.

At the same time, patients in the TTV-guided group had lower tacrolimus levels and received lower daily doses. A statistically significant reduction in infections was not demonstrated in this study. However, the results suggest that in stable, low-risk patients, a reduction in immunosuppression may be possible without compromising the safety of the transplanted organ.

“The result is an important step towards personalised transplant medicine,” says Bond. “TTV measurement is approved for clinical use, cost-effective, easy to measure and readily standardised. This approach therefore has the potential to be widely used in further clinical trials and, later, possibly in routine clinical practice.”

Milestone for academic transplant research

The TTVguideIT study was part of the EU-funded Horizon 2020 project TTVguideTX. The project was coordinated by MedUni Vienna and received over six million euros in funding over five and a half years. A total of 20 partners from ten European countries were involved, including university transplant centres, virology, study coordination, ethics, biostatistics and industry partners.

From an Austrian perspective, the project was also structurally significant: at the time, it was the largest investigator-driven randomised clinical trial in Austria. For the first time, all four Austrian transplant centres collaborated on a randomised clinical trial. Furthermore, TTVguideIT was the first academic study to be submitted to the EU’s Clinical Trials Information System.

Scientifically, the study marks several steps into a new field: it is the first study in which immunosuppression following organ transplantation was controlled using a biomarker, and the first multicentre biomarker study in the field of organ transplantation to achieve its primary endpoint.

Further research is already underway

The findings initially apply to stable, low-risk adult kidney transplant recipients in the first year following transplantation. Whether and how the approach can be applied to other patient groups, later periods following transplantation, or other organ transplants must be investigated in further studies.
A follow-up multicentre study is currently underway in France. It is investigating the TTV-guided approach in patients from the second year post-transplant onwards. The aim is to clarify whether personalised management of immunosuppression can also provide additional benefits in later phases following transplantation.

About TTVguideTX
TTVguideTX was a research project funded by the European Union under Horizon 2020 to develop and clinically trial a new tool for managing immunosuppression following kidney transplantation. The approach is based on measuring Torque-Teno-virus in the blood. The aim was to better assess the balance between adequate protection against organ rejection and the lowest possible risk of infection. Website: https://www.ttv-guide.eu

Publication:
Presentaion at ERA 26 in Glasgow
Torque Teno Virus-Guided vs. Standard Immunosuppression in Kidney Transplant Recipients: The TTVguideIT Randomised Controlled Trial
Frederik Haupenthal, Felix Herkner, Sebastian Kapps, Konstantin Doberer, Jette Rahn, Carole Janis, Marta del Álamo, Georg Melzer-Venturi, Fabrizio Maggi, Hannes Neuwirt, Kathrin Eller, Daniel Cejka, Christian Hugo, Miriam Banas, Klemens Budde, Ondřej Viklický, Paolo Malvezzi, Sophie Caillard, Joris Rotmans, Jip Jonker, Isabel Beneyto, David Navarro, David Rodriguez-Arias, Heinz Regele, Matthias Vossen, Franz König und Gregor Bond für die TTVguideTX Consortium Partners und die TTVguideIT Investigators

Study Protocol
A multicentre, patient- and assessor-blinded, non-inferiority, randomised and controlled phase II trial to compare standard and torque teno virus-guided immunosuppression in kidney transplant recipients in the first year after transplantation: TTVguideIT.
Haupenthal F, Rahn J, Maggi F, Gelas F, Bourgeois P, Hugo C, Jilma B, Böhmig GA, Herkner H, Wolzt M, Doberer K, Vossen M, Focosi D, Neuwirt H, Banas M, Banas B, Budde K, Viklicky O, Malvezzi P, Rostaing L, Rotmans JI, Bakker SJL, Eller K, Cejka D, Pérez AM, Rodriguez-Arias D, König F, Bond G; TTVguideTX consortium partners.
Trials. 2023 Mar 22;24(1):213. doi: 10.1186/s13063-023-07216-0.

Statisitical Analysis Plan

Statistical analysis plan for TTVguideIT-a multicentre, patient- and assessor-blinded, non-inferiority, randomised and controlled phase II trial to compare standard and Torque Teno virus-guided immunosuppression in kidney transplant recipients in the first year after transplantation. Herkner F, Haupenthal F, Kapps S, Doberer K, Herkner H, König F, Bond G. Trials. 2025 Oct 23;26(1):432. doi: 10.1186/s13063-025-09119-8.

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Medical University of Vienna – Brief Profile

The Medical University of Vienna (MedUni Vienna for short) is one of Europe's most traditional centres for medical education and research. With around 8,600 students, it is now the largest medical training institution in the German-speaking world. With more than 6,500 staff, 30 university hospitals and two clinical institutes, twelve centres for medical theory and numerous highly specialised laboratories, it ranks among Europe's leading research institutions in the biomedical field. MedUni Vienna also houses the Josephinum, a museum of medical history.