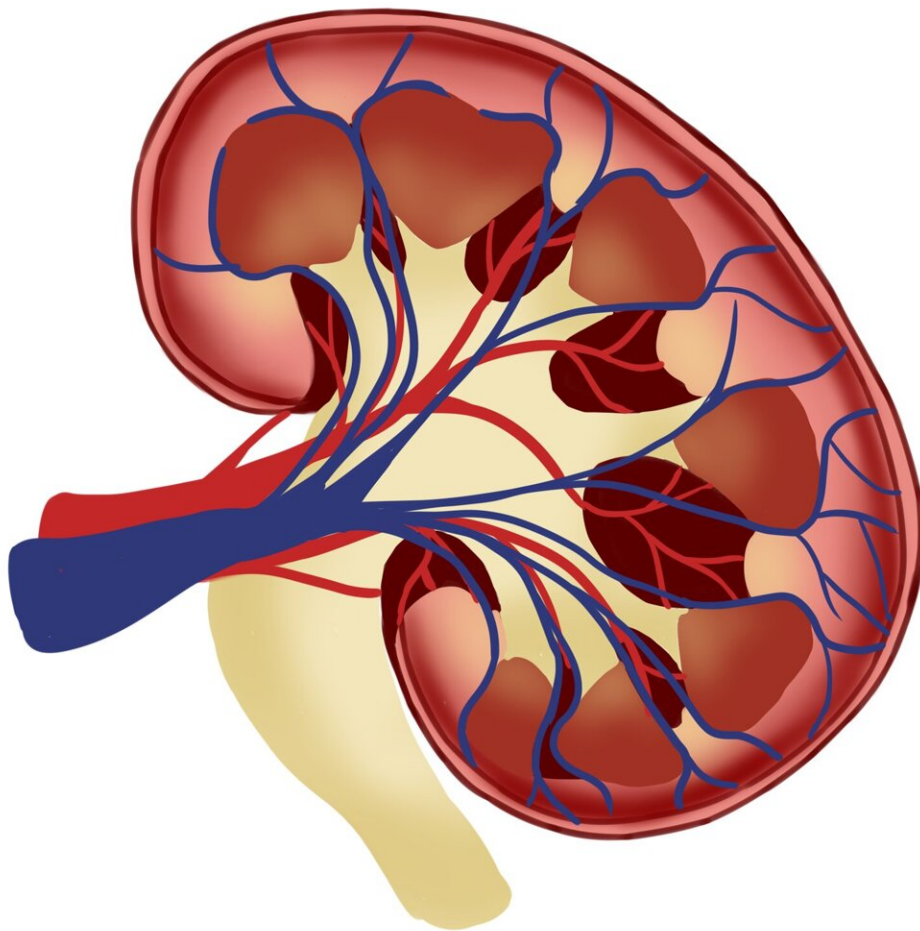


New therapy proven effective against rejection in kidney transplantation

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Antibody-mediated rejection (AMR) is one of the most common causes of kidney transplant failure. To date, however, no treatment has proven effective in combating this complication in the long term.

As part of an international and multidisciplinary clinical study led by Georg Böhmig and Katharina Mayer, Clinical Division of Nephrology and Dialysis, Department of Medicine III at MedUni Vienna and University Hospital Vienna, a new therapeutic principle in [transplant medicine](#) has been found to be both safe and highly effective. The results were recently [published](#) in the *New England Journal of Medicine*.

The research involved 22 patients who were diagnosed with antibody-mediated rejection (AMR) following a kidney transplant at the University Hospital Vienna and Charité–Universitätsmedizin Berlin between 2021 and 2023. In a randomized, double-blind and placebo-controlled study design, patients were given either the substance felzartamab or an agent with no pharmacological effect (placebo).

Felzartamab is a specific (monoclonal CD38) antibody, originally developed as an immunotherapy to treat multiple myeloma by eliminating tumor cells in the bone marrow.

"Due to its unique ability to influence immune reactions, felzartamab also attracted interest in transplantation medicine," says study leader Böhmig, explaining recent developments that are largely attributable to his initiative.

"Our goal was to assess the safety and efficacy of the antibody as a potential treatment option for AMR after kidney transplantation," adds first author Mayer.

After a six-month treatment period and an equivalent observation period, the researchers were able to report promising results: most notably,

morphological and molecular analyses of transplant biopsies indicate that felzartamab has the potential to effectively and safely combat AMR of kidney transplants.

Possible breakthrough achieved

With about 330 transplants performed each year, kidney transplantation is the most common form of organ transplantation in Austria. AMR is one of the most common complications, occurring when the organ recipient's immune system develops antibodies against the foreign organ. This can result in loss of kidney function, often resulting in the need for further dialysis or even a repeat transplant.

Treating AMR is therefore essential not only for the health of patients, but also for the efficient use of donor organs, which are already in limited supply. "The results of our study could represent a breakthrough in the treatment of [kidney transplant](#) rejection," summarizes Mayer.

"Our findings also raise the hope that felzartamab could counteract the rejection of other donor organs, such heart or lung transplants. Xenotransplants using genetically modified pig organs could perhaps also move further into the realm of possibility," says Böhmig.

This interdisciplinary Phase II study, the first clinical research project to demonstrate an effective treatment for late AMR, was conducted in collaboration with several departments at MedUni Vienna and University Hospital Vienna, including the Department of Clinical Pharmacology (Bernd Jilma).

It also involved international collaborations with Charité–Universitätsmedizin Berlin (Klemens Budde), University Hospital Basel, the University of Alberta, Canada, and the US start-up Human Immunology Biosciences, among others. The next step, which is

crucial for [drug approval](#), is to validate the results in a multicentre Phase III study, currently being planned based on the current study results.

More information: Katharina A. Mayer et al, A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection, *New England Journal of Medicine* (2024). [DOI: 10.1056/NEJMoa2400763](https://doi.org/10.1056/NEJMoa2400763)

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