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## **Polycystic kidney disease: Study explores diet as a key factor in kidney disease**

*A new clinical study at the University of Cologne and Cologne University Hospital is investigating whether a ketogenic diet has a positive effect on patients with polycystic kidney disease / The trial is funded by the American PKD Foundation (polycystic kidney disease)*

A team of researchers at the University of Cologne is launching a study on the effects of ketogenic dietary regimens in patients affected by hereditary polycystic kidney disease (ADPKD). Ketogenic diets are characterized by a low intake of carbohydrates in combination with increased fat consumption. Headed by Professor Dr Roman-Ulrich Müller, senior physician at the Department II of Internal Medicine at Cologne University Hospital and research group leader at the Cluster of Excellence for Aging Research CECAD as well as at the Center for Molecular Medicine Cologne (CMMC), and Dr Franziska Grundmann, senior physician and head of the Clinical Study Center at the Department II of Internal Medicine, the ‘first in men’ – translational study Keto-ADPKD will enrol 63 participants.

Basic research has already shown a positive effect of ketogenic diets on polycystic kidney disease in rodent models. Müller’s collaborator, the University of Cologne Alumnus Professor Dr Thomas Weimbs, University of California, Santa Barbara, published these data in 2019 in *Cell Metabolism*. He will support the trial as scientific advisor.

Polycystic kidney disease affects about one in 1,000 people worldwide. In Germany, this results in approximately 80,000 ADPKD patients. About half of these patients suffer from significant renal function impairment with advancing age. The current study is funded by the U.S. PKD Foundation, a non-profit organization focused on polycystic kidney disease research. ‘We are proud to receive this support and very pleased that we can conduct this study here in Cologne. It is rare that nutrition studies, which are costly and time-consuming, are funded,’ said Müller.

Coordinated by the Clinical Study Center of the Department II of Internal Medicine, the current study investigates for the first time the feasibility, safety, and efficacy of ketogenic dietary regimens in polycystic kidneys in humans in three groups à 21 patients. In ketogenic diets, the main part of the calories supplied comes from fats. The regimens used in the trial aim for healthy high-fat food sources. Very few carbohydrates (sugars) are consumed. The body adapts to the diet and switches its metabolism from carbohydrate/sugar burning (glycolysis) to ketosis, the burning of fats. Studies using rodent models of polycystic kidney disease have already shown that the metabolic state of ketosis is important in inhibiting the progression of this disease since the cyst-lining cells cannot adapt to the altered metabolism. In the current study, one treatment arm does not change the usual diet (control group), the second arm receives a ketogenic diet plan, and the third group eats as usual but performs water fasting (water intake only) once a month for three days.

In polycystic kidney disease, the functional units of the kidneys, the nephrons, are affected. They develop cysts – sacs filled with fluid – which can significantly impair kidney function. More than 50 per cent of these patients will lose their kidney function by 50-60 years of age and will depend on renal-replacement therapies such as dialysis or kidney transplantation. ‘Preserving kidney function is the primary goal. It is tremendously important to develop preventive measures for those affected. But the potential effect on kidney growth by cyst formation associated with the disease, which often causes discomfort, is also important,’ Müller remarked. Grundmann added: ‘It is of key interest to expand the scientific data on ketogenic diets. Data from randomized trials on safety and efficacy are very limited so far, especially in patients with kidney disease. We are curious to see whether this approach will show a similarly positive effect in patients as observed in preclinical studies.’

The study is planned for a period of about one and a half years. First results are expected in fall 2022.

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<https://clinicaltrials.gov/ct2/show/NCT04680780?cond=ADPKD&draw=2&rank=>

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