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ERA Long-Term Research Fellowship Project

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Project's key info

Title of the project	Safety of healthy versus restricted potassium plant-based diet for patients with chronic kidney disease: A pilot study (Acronym: SAFE K)
Working Group involved in the project	Nutrition working group
Principal Investigator(s) of the project	Carla Maria Avesani
Duration	12 months
Fellowship Grant	35.225,00 €
Start of the fellowship	Within 6 months after notification of the grant award to the fellow.

Receiving Institute

Name of receiving institute	Karolinska Institute
Supervisor's name	Carla Maria Avesani
Supervisor's e-mail address	carla.avesani@ki.se

Project's detailed description

Project description
This project proposes a pilot randomized clinical trial to evaluate the safety and potential benefits of an unrestricted healthy plant-based diet in patients with moderate to advanced chronic kidney disease (CKD) who are not yet on dialysis. Traditionally, CKD patients have been advised to restrict dietary potassium to prevent hyperkalemia. However, recent evidence indicates that potassium intake from whole plant foods is not strongly associated with hyperkalemia and that restrictive diets may reduce quality of life and overall diet quality. Limiting fruits, vegetables, legumes, whole grains, and nuts may also lead to increased consumption of processed foods containing highly bioavailable potassium additives, potentially worsening potassium balance. Conversely, diets rich in whole plant foods have been associated with multiple metabolic benefits, including improved acid–base balance, reduced inflammation, improved gut microbiota, lower uremic toxin production, and better phosphate control. Building on previous feasibility work, this study shifts the focus from potassium restriction to the introduction of healthy plant-based foods. Patients will be randomized for six months to either a healthy plant-based diet, with higher intakes of fruits, vegetables, legumes, whole grains, and nuts, or a standard-of-care restricted plant-based diet, which limits potassium-rich foods. Both diets will be supported by renal dietitians, and weekly food baskets will be provided to enhance adherence. The primary objective is to assess whether the healthy plant-based diet is safe and does not increase the incidence of hyperkalemia compared with the restricted diet. Secondary objectives include evaluating effects on quality of life, treatment satisfaction, and markers of metabolic acidosis, inflammation, uremic toxins, phosphate balance, and proteinuria.

The study will be conducted as a parallel randomized pilot trial with a six-month follow-up at Karolinska University Hospital. Patients will undergo regular clinical, biochemical, nutritional, and patient-reported outcome assessments, with predefined safety protocols for potassium management. Data will be analysed using both intention-to-treat and per-protocol approaches. Ethical approval has been requested, and the study will be registered on ClinicalTrials.gov. Results will be published in open-access journals, with appropriate acknowledgment of ERA support for the Long-Term Fellow involved in the project.

Goals of the project

The project aims at:

1. Evaluating the safety of unrestricted healthy plant-based diets (Healthy-PBD).
   The study will investigate whether an unrestricted diet rich in fruits, vegetables, legumes, whole grains, and nuts increases the risk of hyperkalemia (plasma potassium >5.5 mmol/L) compared with a standard restricted plant-based diet (Restricted-PBD) in patients with moderate to advanced CKD not receiving dialysis.
2. Assessing secondary metabolic and clinical effects of Healthy-PBD.
   Beyond potassium levels, the study will explore additional metabolic parameters—such as acid–base balance, inflammation markers, and gastrointestinal well-being—to understand the broader physiological implications of unrestricted plant-based diets.
3. Examining the impact on patient-reported outcomes.
   The study will assess quality of life, treatment satisfaction, and dietary adherence, thereby integrating patient perspectives into nutritional management and improving understanding of how dietary strategies influence daily life and well-being.
4. Generating pilot data for a larger multicenter trial.
   The pilot study will provide essential feasibility and safety data, including recruitment, retention, adherence, and outcome variability, forming the evidence base required to design a future multicenter randomized controlled trial.
5. Strengthening research capacity in renal nutrition science.
   Through advanced methodological training and mentorship under the ERA Long-Term Fellowship, the researcher will enhance expertise in clinical trial design, biostatistics, and patient-centered outcomes research—aligning with ERA's mission to foster research excellence and innovation in nephrology.
6. Promoting knowledge dissemination and scientific collaboration.
   The fellowship will facilitate collaboration between European research institutions and clinical centers, ensuring that study findings are disseminated through peer-reviewed publications, ERA symposia, and professional networks, ultimately informing clinical practice across Europe.

Qualifications and/or expertise required to the fellow

Mandatory requirements
Nephrologists and those with degree in biomedicine with documented experience in Nutrition, or a Dietitian / nutritionist with documented experience renal disease.
Concluded PhD in science when the fellowship begins.
Fluency in spoken and written English

Desirable requirements
Publications in the field of Nutrition and renal diseases.
Basic knowledge in biostatistics.
Concluded a master's degree in nutrition or nephrology or a PhD in science.