

Abstract citation ID: gfae069.1499

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## A multicenter and randomized study of a VLPD supplemented with ketoanalogues in patients with advanced CKD in Spain. Adherence study

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**Background and Aims:** Clinical guidelines recommend a very low-protein diet (VLPD) supplemented with ketoanalogues (KAs) for patients with advanced chronic kidney disease (CKD) to reduce progression (evidence 1A) and improve the quality of life (evidence 1C). However, there is no prior experience with this nutritional intervention in Spain.

**Method:** A multicenter, randomized, and controlled study that evaluated adherence to a VLPD supplemented with KAs (Ernamin®) in non-dialysis dependent CKD patients, estimated using the Morisky scale. Secondary objectives included assessing the effect of VLPD + KAs on kidney function, urine protein, albumin levels and other metabolic and nutritional parameters, including changes in body composition stores, at months 0, 1, 3, 6, and 9.

**Results:** Preliminary data from 33 patients (67% men; mean age  $68 \pm 10$ ; GFR  $16.7 \pm 3.9$  ml/min/1.73 m<sup>2</sup>), randomized into 2 groups, are presented.

The VLPD group showed good acceptance and tolerance of the diet and supplement, with medium or high adherence in 80% of patients from the first month, maintained throughout the study (Figure).

The use of VLPD was associated with a decrease in phosphorus levels ( $-0.4$  mg/dl VLPD vs.  $0.09$  mg/dl LPD,  $P = 0.027$ ) and C-reactive protein (CRP) levels ( $-2$  mg/dl VLPD vs.  $0.33$  mg/dl LPD), an increase in calcium levels ( $0.3$  mg/dl VLPD vs.  $-0.2$  mg/dl LPD,  $P = 0.015$ ), and an increase in muscle mass (LTM) measured by bioimpedance ( $3.7$  kg VLPD vs.  $-0.6$  kg LPD,  $P = 0.03$ ). Stability in weight, fat mass, extracellular volume, albumin levels, and MIS scale was observed during the follow-up. Estimated glomerular filtration rate, and urine protein remained unchanged in both groups.

**Conclusion:** Protein restriction associated with KAs shows good short-term tolerance and acceptance. This study confirms several effects associated with VLPD supplemented with KAs, including an anti-inflammatory effect, the preservation of nutritional status, and a better control of phosphate levels. These data suggest safe protein intake restriction with stabilization of protein stores.

