



## 29<sup>th</sup> International Conference on **Clinical Diabetes, Diabetic Medication & Treatment**

### **Beneficial effects of Ketogenic Diet for Breast Cancer Treatment: A Randomized Controlled Clinical Trial**

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**Background:** Despite recent interest in the use of ketogenic diets (KDs) for cancer, evidence of beneficial effects is lacking. The present study aimed to evaluate the effects of a KD in patients with locally advanced and metastatic breast cancer receiving chemotherapy.

**Methods:** A total of 80 patients undergoing treatment with chemotherapy were randomly assigned to KD or control group for 12 weeks. Concurrent with the admission, midway point, and at 12 weeks, fasting blood samples were collected for evaluation of kidney and liver markers, lipid profile, FBS, ketone bodies, insulin, IGF-1, CEA, CA15-3, ESR, CRP, IL-10, and TNF- $\alpha$ . Quality of life and physical activity were assessed. Sonography for patients with locally advanced disease and CT or MRI scans for patients with metastatic disease were done on admission and at 12 weeks. At the completion of the chemotherapy, patients with locally advanced disease underwent surgery and stage was recalculated. Also patients with metastases were evaluated for response rate.

**Results:** No severe adverse side effect was found regarding lipid profile and kidney or liver marker. TNF- $\alpha$  decreased significantly after 12 weeks of treatment (MD: 0.64 [CI 95%:  $-3.7, 5$ ]  $P < 0.001$ ), while IL-10 increased (MD: 0.95 [CI 95%:  $-1, 3$ ]  $P < 0.001$ ) in the intervention compared to the control group. Patients in the KD group had lower adjusted serum insulin compared to the control group (MD:  $-1.1$  [CI 95%:  $-3, 1$ ]  $p < 0.002$ ). KD lead to a reduction in tumor size in the KD compared to the control (27 vs 6 mm,  $P < 0.01$ ). Stage decreased significantly in patients with locally advanced disease in the KD group after 12 weeks ( $P < 0.01$ ). No significant differences were seen in quality of life or physical activity scores between the two groups after 12 weeks. No significant differences in response rate were observed in patients with metastatic disease. The overall survival rate was higher in KD group compared to the control group in neoadjuvant patients ( $P < 0.04$ ).

**Conclusions:** KD in breast cancer patients is safe and might exert beneficial effects through decreasing TNF- $\alpha$  and insulin and increasing IL-10. KD may result in a better response through reductions in tumor size and downstaging in patients with locally advanced disease. In addition, KD can improve the overall survival in neoadjuvant patients. However, more studies are needed to elucidate the potential beneficial effects of KD in patients with metastases.

**Trial registration:** This trial has been registered on Iranian Registry of Clinical Trials (IRCT) under the identification code: IRCT20171105037259N2.