

# iSLICE: Does a ketogenic diet have beneficial effects on patients with breast cancer? a randomized controlled clinical trial

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## Abstract

**Background:** Ketogenic metabolic therapy (KMT) using ketogenic diets (KD) is emerging as viable alternative or complementary strategy for managing cancer; however, few clinical trials have been reported. 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 insulin, IGF-1, CEA, CA15-3, ESR, CRP, IL-10, and TNF- $\alpha$ . 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:** 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 in response rate were observed in patients with metastatic disease.

**Conclusions:** KMT in breast cancer patients 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; however, more studies are needed to elucidate the potential beneficial effects of KD in patients with metastases

## Biography:

I am Dr Adeleh Khodabakhshi, PhD of clinical nutrition and faculty member of Kerman University of Medical Sciences --Cohen CW, Fontaine KR, Arend RC, Gower BA. A ketogenic diet is acceptable in women with ovarian and endometrial cancer and has no adverse effectson blood lipids: a randomized, controlled trial. *Nutr Cancer* 2020;72:584e94.

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