

Lifestyle and breast cancer recurrences: The DIANA-5 trial

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ABSTRACT

Aims and background. The DIANA (Diet and Androgens)-5 study is a multi-institutional randomized controlled trial of the effectiveness of a diet based on Mediterranean and macrobiotic recipes and principles, associated with moderate physical activity, in reducing additional breast cancer events in women with early stage invasive breast cancer at high risk of recurrence because of metabolic or endocrine milieu. The intervention is expected to reduce serum insulin and sex hormones, which were associated with breast prognosis in previous studies.

Methods. Between 2008 and 2010, the study randomly assigned 1208 patients to an intensive diet and exercise intervention or to a comparison group, to be followed-up through 2015. General lifestyle recommendations for the prevention of cancer are given to both groups, and the intervention group is being offered a comprehensive lifestyle intervention, including cooking classes, conferences, common meals and exercise sessions. Adherence assessments occurred at baseline and at 12 months and are planned at 36 and 60 months. They include food frequency diaries, anthropometric measures, body fat distribution assessed with impedance scale, one week registration of physical activity with a multisensor arm-band monitor, metabolic and endocrine blood parameters. Outcome breast cancer events are assessed through self report at semi annual meetings or telephone interview and are validated through medical record verification.

Results. The randomized groups were comparable for age (51.8 years), proportion of ER-negative tumors (22%), axillary node metastasis (42%), reproductive variables, tobacco smoking, blood pressure, anthropometric measurements and hormonal and metabolic parameters.

Conclusions. DIANA-5 has the potential to establish whether a Mediterranean-macrobiotic lifestyle may reduce breast cancer recurrences. We will assess evidence of effectiveness, first by comparing the incidence of additional breast cancer events (local or distant recurrence, second ipsilateral or contralateral cancer) in the intervention and in the control group, by an intention-to-treat analysis, and second by analyzing the incidence of breast cancer events in the total study population by compliance assessment score.

Key words: breast cancer, diet, physical exercise, randomized trial, recurrence, survival.

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