Randomized phase III clinical trial of a combined treatment with carnitine + celecoxib ± megestrol acetate for patients with cancer-related anorexia/cachexia syndrome.


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BACKGROUND & AIMS: A phase III, randomized non-inferiority study was carried out to compare a two-drug combination (including nutraceuticals, i.e. antioxidants) with carnitine + celecoxib ± megestrol acetate for the treatment of cancer-related anorexia/cachexia syndrome (CACS): the primary endpoints were increase of lean body mass (LBM) and improvement of total daily physical activity. Secondary endpoint was: increase of physical performance tested by grip strength and 6-min walk test.

METHODS: Sixty eligible patients were randomly assigned to: arm 1, l-carnitine 4 g/day + Celecoxib 300 mg/day or arm 2, l-carnitine 4 g/day + celecoxib 300 mg/day + megestrol acetate 320 mg/day, all orally. All patients received as basic treatment polyphenols 300 mg/day, lipoic acid 300 mg/day, carbocysteine 2.7 g/day, Vitamin E, A, C. Treatment duration was 4 months. Planned sample size was 60 patients.

RESULTS: The results did not show a significant difference between treatment arms in both primary and secondary endpoints. Analysis of changes from baseline showed that LBM (by dual-energy X-ray absorptiometry and by L3 computed tomography) increased significantly in both arms as well as physical performance assessed by 6MWT. Toxicity was quite negligible and comparable between arms.

CONCLUSIONS: The results of the present study showed a non-inferiority of arm 1 (two-drug combination) vs arm 2 (two-drug combination + megestrol acetate). Therefore, this simple, feasible, effective, safe, low cost with favorable cost-benefit profile, two-drug approach could be suggested in the clinical practice to implement CACS treatment.