

A double-blind, placebo-controlled randomized trial phase IIa, evaluating the effect of curcumin for the treatment of cancer anorexia-cachexia syndrome in patients with stage III-IV of head and neck cancer (CurChexia)

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Background: The cancer anorexia-cachexia syndrome (CAS) is a significant comorbidity in all cancer patients that increase the mortality rate. Almost all head and neck cancer patients suffered from this syndrome. CAS cause increases energy expenditure by increase systemic inflammation and decreases energy consumption due to anorexia. Conduce to skeleton muscle breakdown and affect the quality of life. Nutritional interventions and primary cancer treatment are the mainstays to treat this situation. However, a vicious cycle causes CAS to persist, especially in head and neck cancer, where tumour location and its treatment interfere with nutritional intervention. Curcumin shows the effect of anti-inflammatory effects, including modulated CAS in animal and in vitro studies.

Objective: To determine the effect of curcumin to treat cancer anorexia-cachexia syndrome in currently treated locally advanced or advanced head and neck cancer patients.

Methods: This is a randomized, double-blind, placebo-controlled phase IIa study. Twenty patients with CAS in locally advanced or advanced head and neck cancer who are adequately fed via a feeding tube were enrolled and randomized in 1:1 to receive oral curcumin (at a dose of 4000 mg daily) (n=10) or placebo (n=10) for eight weeks. The primary endpoint was body composition (muscle mass, body fat mass, and basal metabolic rate). The secondary endpoints were handgrip muscle strengthening, body mass index, absolute lymphocyte count, and safety and toxicity.

Results: There is statistical significance benefit from curcumin on improvement of muscle mass compare to placebo (2.16% [95% Confident interval; CI, -0.75 to 5.07] vs -3.82% [95% CI, -8.2 to 0.57]; P = 0.019). The others parameter of body compositions are not statistical significant but tend to favour curcumin benefit. The body fat mass(-0.51 [95% CI, -21.89 to 20.86] vs -8.97% [95% CI, -19.43 to 1.49]; P = 0.432) and percentage of mean change in the basal metabolic rate (BMR) (0.54% [95% CI, -1.6 to 2.67] vs -1.61% [95% CI, -4.05 to 0.84]; P = 0.153). Notably, patients with curcumin was less reduction in handgrip muscle strengthening and absolute lymphocyte count but not statistical significant. Most adverse events were grade 1 on both groups similarly.

Conclusions: The curcumin add-on resulted in a significant increase in muscle mass than standard nutritional support. Furthermore, it may improve and delay a decrease in the other body compositions, handgrip strength, and absolute lymphocyte count. Curcumins were safe and well-tolerated. This is an unmet need for clinical trials.