
A phase III randomized study comparing the effects of oxandrolone (Ox) and megestrol acetate (Meg) on lean body mass (LBM), weight (wt) and quality of life (QOL) in patients with solid tumors and weight loss receiving chemotherapy.

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Abstract: **Background:** Involuntary wt loss is a significant problem in patients (pts) with cancer which disproportionately represents a loss of muscle mass. Ox is a potent oral anabolic steroid exhibiting minimal androgenic effects which promotes wt gain primarily through an increase in LBM. **Methods:** We performed a prospective, randomized phase 3 trial comparing the effects of Ox (10mg bid) and MA (800mg qd) on wt, body composition and QOL in adult pts with solid tumors and wt loss receiving chemotherapy. Body composition was serially assessed by Bioelectrical Impedance Analysis. The impact of these agents on QOL was evaluated using the FACT-G and the Anorexia/Cachexia subscale. The primary outcome was LBM after 12 weeks of drug therapy. Secondary outcomes included wt, fat mass, and QOL. Linear mixed effects models were used to assess the effect of treatment on these outcomes over time. **Results:** 155 pts were randomized and the study has been completed. Baseline demographics: median age 64 years; 41% female; 63% stage 4; performance status 0/1/2=8%/61%/31%; even distribution between study arms. At 12 weeks, significant changes from baseline were observed for wt (lbs) (Ox -3.4 vs MA +5.8, p<.001) and fat mass (Ox -4.89 vs MA +2.68, p<.001). An increase in LBM (lbs) (Ox 2.7 vs MA 0.8; p=.11) was observed but did not reach statistical significance. Neither treatment impacted global QOL or fatigue, but both showed improvement on the subscale (Ox 6.7 vs MA 11.3; p=.01). Eleven serious adverse events (Ox 4, MA 7) were attributed as at least possibly related to study drug. Only 50% of pts (Ox 39%, MA 63%) remained on study at 12 weeks; a dropout rate consistent with similar palliative care trials. **Conclusions:** Pts treated with Ox still lost wt but experienced an increase in LBM, a reduction in fat mass and reduced self-reported anorectic symptoms. MA therapy was associated with an increase in weight and fat mass, minimal change in LBM and improved appetite. The complementary effects of the two agents on appetite, overall wt gain and LBM suggest that their combination may result in optimal effects in a similar pt population. Supported by NCI grant 1 U10 CA8185 and Savient Pharmaceuticals, Inc.
