TPS6120 **Poster Session**

A phase II randomized trial of nano-crystalline megestrol acetate for nutritional improvement in postoperative head and neck squamous cell carcinoma undergoing radiotherapy.

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Background: Head and neck squamous cell carcinoma (HNSCC) patients frequently experience malnutrition and weight loss, exacerbated by cancer cachexia and treatment-related side effects during concurrent radiotherapy. Nano-crystalline megestrol acetate (NMA) improves bioavailability and efficacy compared to conventional formulations, demonstrating enhanced appetite, weight gain, and quality of life (QoL) in cancer cachexia. **Methods:** This randomized, parallel-controlled Phase II trial evaluates the efficacy and safety of NMA in improving nutritional outcomes in HNSCC patients undergoing postoperative CCRT. The study enrolls 96 HNSCC post-surgery patients. Participants are stratified by pre-treatment weight loss ($>5\%$ vs. $\leq 5\%$) and standard treatment regimen (radiotherapy vs. concurrent chemoradiotherapy), then randomized 1:1 to receive NMA (625 mg/day) plus standard treatment or standard treatment alone. The novel aspects of this design include the use of a nano-crystalline formulation to overcome absorption challenges, allowing effective drug delivery in fasting states. Additionally, comprehensive endpoints assess appetite status (A/CS-12 score), weight changes, lean body mass, inflammatory and nutritional markers, and QoL, providing an integrated evaluation of nutritional and clinical benefits. 12 of planned 96 patients have been enrolled. Clinical trial information: NCT06772428. Research Sponsor: None.