The Effect of Cyproheptadine Hydrochloride (Periactin) and Megestrol Acetate (Megace) on Weight in Children with Cancer/Treatment Related Cachexia (HLMCC0205)

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Synopsis:

This is a sequential Phase II study of cyproheptadine hydrochloride and megestrol acetate administered daily to 70 pediatric oncology patients with a history of disease and/or treatment-related weight loss.

The primary objective of this study is to estimate the efficacy of cyproheptadine hydrochloride (Periactin) in preventing further weight loss in children with cancer associated cachexia. In those patients who do not respond to cyproheptadine hydrochloride (Periactin), the objective is to investigate how cyproheptadine hydrochloride and megestrol acetate affect body protein and fat levels.

All patients consent to participate in the study prior to randomization. Children between the ages of 2-21 with non-hormonally sensitive cancers and are not on appetite stimulants are eligible to participate in the study. Medical evaluation and weight measurements are collected at baseline and every four weeks. Laboratory evaluations are collected at baseline, after 4 weeks on Periactin and 4-week follow-up to measure pre-albumin and serum leptin. Patients will be weighed after receiving 4 weeks of Periactin. If the patient’s weight is stable or increased, they will return in 4 weeks for follow up and complete the study. If the patient has lost weight after 4 weeks on Periactin, they will switch to Megace. Prior to initiating Megace, additional laboratory testing is done to measure glucose, cortisol, lipid profile and testosterone (males > 10 years of age) or estradiol (females > 10 years of age). Patients will be weighed after completing a 4 week course of Megace and blood will be drawn for repeat laboratory testing. A follow up visit takes place 4 weeks later to complete the study. All patients complete daily logs to document study agent intake and adverse events and return them to study staff at their clinical visits.