Combination therapy with Propranolol and Mirtazapine in Cancer anorexia cachexia syndrome – A feasibility trial (Concept paper)

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**Background**

The adverse effects of Propranolol namely Fatigue and loss of appetite have the potential to have a deleterious impact on the quality of life. Mirtazapine is a centrally acting 5HT receptor antagonist with nor adrenergic reuptake inhibiting properties which has been shown to be effective in improving appetite in this patient population.

**Aim**

To assess feasibility of recruitment, compliance with treatment and safety profile of combination therapy with Propranolol and Mirtazapine in CACS.

**Primary objective**

To assess the feasibility of treatment in advanced cancer population with PG-SGA scores of more than 6.5.

**Study design**

Phase 2 feasibility trial

**Study population**

Patients with a histopathologically proven diagnosis of advanced cancer with anorexia cachexia

**Intervention**

**Study arm**

Propranolol 40 mg two times daily

Mirtazapine 15 mg at night

**Duration of treatment**

6 weeks

**Outcomes, measures and comparison**

Percentage of patients in Minimally clinically important difference in PG-SGA scores

Percentage of patients with improvement of 0.6 points in Appetite on Numerical rating scale at 3 and 6 weeks.

Number of patients with grade 2 or more fatigue

Number of patients who meet discontinuation criteria (based upon reduction in Appetite) at 3 weeks

Trend of change in Weight (loss of 0.8 kg over 6 weeks expected in CACS)

**Significance**

The success of this trial has the potential to provide an effective and affordable treatment option and lead to a more conclusive answer to the utility of combination therapy in this setting. This treatment modality targets both resting energy expenditure and reduction in appetite.