Role of Enhancing Serotonin Receptors Activity for Sleep Apnea Treatment in Patients With SCI

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Study Protocol: A pilot randomized placebo-controlled cross-over study. Eligible subjects with spinal cord injury were studied on three separate occasions: (1) Buspirone vs. Trazodone vs. placebo for 2 weeks; the participants were blinded to what medication they were taking. The initial dose of Buspirone is 15 mg daily (7.5 mg b.i.d.). Buspirone dosage was increased 5 mg per day at intervals of 2 to 3 days until a maximum dose of 30mg/day is reached. Trazodone was given at 100 mg dose before bed-time. After the two week treatment, a noninvasive nasal mechanical ventilation study was repeated to determine the hypocapnic apneic threshold. (2) Cross over medication for two weeks was followed by a second noninvasive nasal mechanical ventilation study to determine the hypocapnic apneic threshold followed by two weeks washout. (3) Cross over medication for two weeks was followed by another study to determine the hypocapnic apneic threshold. For the baseline hypocapnic apneic threshold the nasal mechanical ventilation study obtained from specific aim 1 was used as a baseline.

Statistical Data analysis: The primary endpoint is the CO_2 reserve ($\Delta P_{ET}CO_2$–AT) which is a marker to measure susceptibility to hypocapnic central apnea, defined as the difference between average end-tidal CO_2 ($P_{ET}CO_2$) for the control breaths on room air and the breaths before the cessation of noninvasive nasal mechanical ventilation. The standard statistical package SPSS (Sigmstat, version 3.5) was used for data analysis. A detailed descriptive analysis of all quantitative data was performed involving the summarization of data, and normal distribution. The primary analysis was repeated measure analysis of variance. In the absence of normal distribution of data, appropriate non-parametric tests were used.