Multicenter, Prospective Clinical Study of Long–acting Intramuscular Testosterone Undecanoate Injection Therapy in the Treatment of Erectile Dysfunction in Hypogonadal Men in Korea

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Background & Objective: Erectile dysfunction (ED) is observed frequently in patients with Late Onset Hypogonadism (LOH) patients. It is also well known that testosterone deficiency underlies several biochemical alterations including neuronal nitric oxide synthase (nNOS) and phosphodiesterase 5 (PDE5) down regulation, leading to ED and unresponsiveness to PDE5 inhibitors. This study aims to evaluate the response of long–acting intramuscular injection of testosterone undecanoate (TU) (NEBIDO®) in LOH patients with ED in Korea.

Design: This study was designed as a multicenter, prospective clinical study investigating the efficacy and safety of long–acting intramuscular injection of TU in patients with LOH and ED. This study included adult males above 18 years of age with the diagnosis of hypogonadism and with the clinical diagnosis of ED. Three injection were given in week 0, 6, 18. Treatment efficacy assessed by International Index of Erectile Function (IIEF) and the Aging Male Symtoms (AMS) scales at screening phase, week 6, 12, 18, and 24. Clinical chemistry, hormone levels, prostate–specific antigen (PSA) and hematocrit were evaluated at screening phase, week 12, and 24.

Results: This study has shown that 1000mg TU injected into male patients with hypogonadism and ED is well tolerated and leads to Testosterone level within a normal ranges. The mean scores of IIEF and Erectile Function (EF) domain were improved significantly at week 24 compared to week 0. The mean scores of AMS and Sexual Factor (SF) domain were also improved significantly at week 24 compared to week 0. Before the next injection, level of serum total testosterone were mostly showed a tendency to decrease with increasing injection interval. The mean trough level of serum total testosterone level were 24ng/ml before the injection. The mean testosterone concentrations of last injection increased with 5.1ng/ml. PSA level were always within normal limit. Injections of TU at intervals of up to 3 months offer an excellent effect. No serious side–effects were noted. Altogether, intramuscular TU appeared to be well suited for testosterone supplement therapy in patients with LOH with ED.

Conclusion: The long–acting intramuscular Testosterone undecanoate injection therapy is an efficient and tolerable modality of testosterone replacement for the patients with late onset hypogonadism and erectile dysfunction in Korean men.