

## **Testosterone Improves Quality of Life, Sexual Function and Delayed Verbal Recall—Randomised Placebo-controlled Study in Hypogonadal Men with Uncontrolled Type 2 Diabetes—STRIDE Study**

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**Objective:** The objective of the study was to assess the effect of long-acting intra-muscular testosterone on Quality of Life (QoL), sexual symptoms, memory and constitutional symptoms in men with hypogonadism and poorly-controlled type 2 diabetes.

**Research design and methods:** This is a randomised double-blinded placebo-controlled add-on trial of intramuscular testosterone undecanoate (Nebido<sup>®</sup>) administered every 12 weeks in 65 hypogonadal men with poorly-controlled diabetes. Phase 1 patients were randomly assigned to either treatment or placebo arm for 6 months of TRT. Phase 2 was an open-labelled phase for 6 months and patients on placebo moved on to the treatment group wherein patients in the treatment group continued. Outcomes (AMS, SF-36, IIEF-5 questionnaires, MMSE (Mini-Mental State Examination), BDHQ (Barnsley Diabetes Hypogonadism Questionnaire) and NERI questionnaire) were assessed at baseline and every 3 months.

**Results:** Mean age of the cohort was 59(42-77) years. Baseline characteristics were comparable between active/placebo groups. Phase 1 - Our study is the first RCT to show a significant reduction in the mean total AMS score from baseline of 48.34±13.13 to 37.72±12.25 at 6 months after testosterone treatment compared to placebo ( $p<0.05$ ). The proportions of patients with severe symptoms moving to a less severe category (low/mild/moderate severity) was 46% in the active vs only 28% in placebo group ( $p=0.0024$ ). There was no significant difference in either the SF-36 scores, MMSE scores, BDHQ, NERI or IIEF-5 scores or its domains at baseline and after 6 months of testosterone treatment. In phase 2 of the trial questionnaires were performed at 0, 3, 6, 9, 12 months on the testosterone and data presented here as significance between 0 and 12 months. The AMS total score ( $p=0.001$ ) and all its subscales (Physical  $p=0.01$ ), Psychological ( $p=0.026$ ) and Sexual ( $p<0.001$ ) with improvement in Libido ( $p<0.001$ ) showed significant improvement. The BDHQ found significant improvement in two domains - Sexual wellbeing ( $p=0.002$ ) and Emotional wellbeing ( $p=0.011$ ) respectively) with the Total score  $p=0.07$ . SF-36 QoL score had improvement in the mean scores of physical health domain ( $p=0.019$ ) and health change domain ( $p=0.019$ ). MMSE found a highly significant improvement in Delayed Verbal Recall ( $p=0.0004$ ). No significant difference to NERI or IIEF-5 scores were found.

**Conclusions:** Our trial is the first RCT to show a significant improvement in sexual symptoms, libido, symptom severity, delayed verbal recall (an important Symptom of Dementia) and constitutional symptoms with TRT in a cohort with poorly-controlled type 2 diabetes and hypogonadism. This study demonstrates that symptoms of hypogonadism can continue to improve up to 12 months. It is important to recognize that men with type 2 diabetes have obesity, complications of diabetes, co-morbidities, erectile dysfunction which all compromise their QoL. An improvement in their QoL and other parameters found in this study represent major improvements in health and life situation.

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