Maximum 3000 characters (including spaces) 1998 characters including spaces. A table counts for 500

Safety of administration of parenteral testosterone undecanoate to mainly elderly men for 48 months

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Introduction & Objectives: To investigate the safety of the administration of long-acting parenteral testosterone undecanoate (TU) to hypogonadal, mainly elderly men.

Materials & Methods: 104 hypogonadal men (38 – 83 years, mean 60.6 ± 8.0 years), with testosterone levels between 4.7 –11.84 nmol/L (N>12.0 nmol/L) (87 had late onset hypogonadism) were treated with parenteral testosterone undecanoate for 4 years as the sole intervention.

Results: Plasma levels of testosterone rose from 9.3 ± 1.7 nmol/L to 18.7 ± 3.1 nmol/L reaching their maximum at 9 months, never exceeding reference values. Further results are presented in table 1. There was a slow but steady increase in prostate volume, paralleled by an increase in serum prostate specific antigen (PSA). PSA never exceeded 4 ng/mL. The residual volume (Res vol) of the bladder decreased over the 48 months, most pronounced in the first 18 months. The scores on the International Prostate Symptoms Score (IPSS) decreased over the 48 month period most pronounced over the 18-24 months. Testis volume (vol) decreased by < 10%. Hemoglobin (HB) and the hematocrit (Hct) increased significantly and had reached its maximum values after 12-18 months. Over the 48 month study period, at any time point, nine patients had a hematocrit above 52%, the upper limit of normal. No specific measures were taken (dose reduction of testosterone, venipuncture). An elevated hematocrit was never found at two occasions in the same patient. Further results are presented in table 1.

Conclusions: Over a period of 48 months testosterone treatment with TU appeared acceptably safe. There was an increase in prostate size and PSA but not in bother.

Longer and larger scale studies are needed. Monitoring individual patients as recommended is necessary. (Wang C et al, Aging Male 2009: 12(1):5-12)