Safety study of long-acting parenteral testosterone undecanoate over 42 months

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

Design & Methods: 122 men aged 34 – 69 years (mean ±SD = 59.5 ± 6.0), with baseline testosterone 5.9 – 12.1 nmol/L (mean ±SD = 2.7 ± 0.5) were treated with parenteral TU. These 122 patients were followed for 42 months.

Results: Plasma levels of testosterone rose from 9.3 ± 1.7 nmol/L to 18.7 ± 2.1 nmol/L, never exceeding reference values. There was a slow but steady increase in prostate volume, not paralleled by an increase in serum prostate specific antigen (PSA) of similar magnitude. Serum PSA rose slightly over the first 24-36 months treatment, stabilizing at levels of 5-10% higher than baseline to rise again after 42 months. PSA never exceeded 4 ng/mL. The residual volume of the bladder decreased over the first 24 months and then stabilized. The scores on the International Prostate Symptoms Score decreased over the first 24 months and then stabilized. The hematocrit increased significantly reaching its maximum after 12 months. Over the 42 month study period, at any time point, nine patients had a hematocrit >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.

Conclusions: Over a period of 42 months testosterone treatment with TU appeared acceptably safe. There was an increase in prostate size and PSA but not in bother. Monitoring individual patients as recommended is necessary.