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Title:

Safety of 42 months of treatment with of long-acting parenteral testosterone undecanoate in men with late-onset hypogonadism

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

Design & Methods: 122 men of a mean age of 59.5 ± 6.0 years, with baseline testosterone $5.9 - 12.1$ nmol/L 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 reaching maximum at 9 months, 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, then values stabilized at levels of 5-10% higher than baseline to rise again after 42 months. PSA never exceeded 4 ng/mL. The residual bladder volume 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. Hematocrit increased significantly and had reached its maximum values after 12 months. Over the 42 month study period, at any time point, nine patients had a hematocrit above 52%, the upper limit of normal. No specific measures were taken. 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 safe. There was an increase in prostate size and PSA but not in bother.