

0115 - SAFETY AND EFFICACY OF TWELVE-WEEKLY TESTOSTERONE UNDECANOATE IN MALE ADOLESCENTS WITH HYPOGONADISM: A MULTICENTRE PILOT CLINICAL TRIAL

Mode: Research paper

Thematic Unit: Puberty

Thematic Unit 2: Growth

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Background/Objectives: Testosterone is essential for normal growth and androgenisation in male adolescents. Testosterone enanthate is used for testosterone replacement therapy in adolescents with delayed puberty. However, lack of adequate clinical trials assessing testosterone formulations prevent widespread use of testosterone undecanoate in paediatric patients. We hypothesised that intramuscular testosterone undecanoate is safe and effective for inducing normal growth and androgenisation in male adolescents with hypogonadism. Aim: To assess the safety and efficacy of a 12-weekly testosterone undecanoate regimen (1 mL = 250 mg every 12 weeks for 6 months, with 1 mL dose increments every 6 months until 4 mL = 1000 mg) for promoting growth and androgenisation in male adolescents with hypogonadism

Methods: This pilot clinical trial was conducted at three hospitals in Argentina. Males aged ≥ 12 years with hypogonadism and Tanner stage G1 or arrested puberty who provided informed consent were included. Subjects with bone age (BA)

Results: Of the 19 patients enrolled, 15 (79%) had central hypogonadism, while 4 (21%) had primary hypogonadism. All males achieved Tanner stage $\geq G4$ after 2 years of therapy. Increases in penile length and width SDS after therapy [mean (SD)] was 0.7 (0.6) and 1.8 (1.5), respectively, with no persisting micropenis. Difference between height at the end of protocol and midparental height [mean (SD)] was 1.0 cm (5.6), while pre-post therapy height gain was 13.9 cm (6.1), p

Conclusion: This is the first clinical trial to assess the safety and efficacy of testosterone undecanoate in male adolescents with hypogonadism. The proposed testosterone undecanoate regimen promoted appropriate growth and androgenisation while maintaining a favourable safety profile and reducing injection burden.

