

PHARMACOKINETICS AND SAFETY OUTCOMES OF GENERIC VERSUS BRANDED TESTOSTERONE PELLETS IN MEN WITH TESTOSTERONE DEFICIENCY- A SINGLE-CENTER, OPEN-LABEL, RANDOMIZED TRIAL

Comment from Jay, 10 75 mg tablets is an impossibility, Testopel will only allow 5, Average dose of 200 mg is 5 so we should be comparing 425 mg Testopel to 1000 mg of Sottopelle.

- [Eliyahu Kresch, BA](#)

Objective

Testosterone deficiency (TD) is characterized by low serum testosterone (T) combined with symptoms such as low energy, fatigue, decreased libido and erectile dysfunction. One of the options to treating TD is with subdermal T pellets. Due to cost and cost and difficulty obtaining insurance reimbursement, we evaluated the pharmacokinetics and safety profile of generic pellets. We performed a single center, open-label, randomized clinical trial evaluating the market brand T pellet - Testopel (75mg) and compared it to generic pellets manufactured by an FDA-registered-outsourcing-facility.

Materials and Methods

We performed an open label randomized clinical trial with TD (at least one hypogonadal symptom + 2 testosterone level <300ng/dL or one low total T level combined with one low free T level). The participants were randomized to one of three groups: 10 pellets of 75mg (750mg), 8 pellets of 100mg/E100 (800mg) and 4 pellets of 200mg/E200 (800mg). Implantation was accomplished using a 3.5mm trocar for the 75mg and 100mg groups and 4.5mm trocar for the 200mg group. Serum testosterone levels, PSA, hematocrit (HCT) and estradiol (E) were measured at baseline before implantation and measured again at 2- and 4-months following implantation.

Results

A total of 73 participants have been enrolled in the ongoing trial (27 Testopel, 26 E100, 20 E200). At 2-month follow up the mean serum testosterone for the Testopel group was 682+/-290 ng/dL, the E100 group was 621+/-248 ng/dL and the E200 was 590 +/-285 ng/dL. At 4-month follow up the mean serum testosterone level for the Testopel group was 367 +/-275 ng/dL, the E100 group was 304 +/-248 ng/dL and the E200 was 387 +/-131 ng/dL. There were no statistically significant differences between testosterone levels of the three groups up to 4 months after implantation. Furthermore, side effects such as polycythemia, changes in E and PSA that can occur with T therapy are similar between men who received the market brand vs generic pellets. Notably, 3 patients in the 200mg group and zero patients in the other groups experienced pellet extrusion.

Conclusions

Market brand and generic testosterone pellets are similar in their ability to increase serum total testosterone to within the normal range (300 – 1000ng/dL) for up to 4 months.

Impact Statement

Our clinical trial demonstrated comparable efficacy and safety between Compounded and commercially available testosterone pellets.

