

# Study finds oral testosterone therapy undecanoate is effective, with no liver toxicity

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An industry-supported study of an oral testosterone replacement therapy (TRT), testosterone undecanoate (TU, brand name Jatenzo) finds it is an effective, long-term treatment for men with low testosterone levels, with no evidence of liver toxicity. The findings are being presented virtually at ENDO 2021, the Endocrine Society's annual meeting.

TST is currently available in multiple modes of [administration](#), including implantable pellets, transdermal gels and intramuscular injections.

"For many men with low [testosterone](#) levels, an oral option is preferred to avoid issues associated with other modes of administration, such as injection site pain or transference to partners and children," said lead researcher Ronald S. Swerdloff, M.D., of the Lundquist Research Institute in Torrance, California. "Before TU was approved, the only orally approved TST in the United States was methyl-testosterone, which was known to be associated with significant chemical-driven [liver damage](#)."

The U.S. Food and Drug Administration approved TU in March 2019, and the medication was made commercially available in February 2020.

Swerdloff conducted a safety and efficacy analysis following two years of TU oral capsule administration in men with low testosterone levels. There were two parts of the study. The first study included men ages 18 to 75 with low testosterone levels who were followed for 12 months. After the first year, 86 men enrolled in the second study, which lasted

for another year.

Over two years, TU kept total testosterone levels in the normal range, with a safety profile relatively consistent with other approved testosterone products. There was no evidence of liver toxicity. There were small but statistically significant increases in prostate specific antigen (PSA), a protein produced by the prostate, and hematocrit (HCT), which measures red blood cell levels. Swerdloff noted these increases are observed with other forms of TST, regardless of modes of administration. The drug had minimal effects on LDL "bad" cholesterol, while lowering HDL "good" cholesterol, as is common with other TRT formulations.

"Our study finds TU is an effective oral therapy for men with [low testosterone levels](#) and has a safety profile consistent with other approved testosterone products, without the drawbacks of non-oral modes of administration," Swerdloff said.

Provided by The Endocrine Society

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