

Testosterone nasal gel works best at three doses a day, study finds

7 March 2015

A new testosterone nasal gel raises men's low testosterone levels to normal, with few side effects, according to the results of a phase 3 clinical trial to be presented Saturday at the Endocrine Society's 97th annual meeting in San Diego.

Last May, the U.S. Food and Drug Administration approved the medication, now called Natesto, making it the only FDA-approved nasal [testosterone](#) replacement therapy, according to the manufacturer, Trimel Pharmaceuticals.

"The unique delivery system makes this a convenient and easy-to-use, self-administered form of testosterone to treat adult males with hypogonadism [low testosterone]," said the study's lead investigator and a consultant to Trimel, Alan Rogol, MD, PhD, who is professor emeritus at the University of Virginia, Charlottesville.

"Also important is that intranasal testosterone minimizes the risk of unwanted secondary exposure of testosterone to women or children," Rogol said.

Testosterone products applied to the skin carry the risk of transferring some of the drug to others who come into close contact. In contrast, the new formulation sends testosterone directly into the nostril. The product comes in a multiple-dose pump dispenser that administers a specified amount of [testosterone gel](#) (5.5 milligrams, or mg) inside each nostril.

The phase 3 clinical trial evaluated the effectiveness and safety of the testosterone nasal gel in 306 men with low testosterone at 39 outpatient centers in the U.S. Men used the treatment for 90 days in both nostrils either twice a day (228 men) or three times a day (78 men) as randomly assigned, to find the most effective dose. They then stayed on the drug for another 90 or 180 days to evaluate tolerance to the medication and effects of treatment.

After 90 days of treatment, the average testosterone concentration in the blood was in the normal range for 90 percent of men who used the nasal gel three times daily, compared with 71 percent of men using it twice a day. (This measure was in the intent-to-treat population: all subjects who received the randomized study drug and had at least one valid postbaseline efficacy measurement.)

The manufacturer's recommended dosing is now three times a day in each nostril, for a total daily dose of 33 mg.

Treatment also strongly improved men's erectile function and mood, Rogol reported.

No serious medical problems related to the medicine occurred in either dosing group, according to the investigators. In addition, Rogol said there were low rates of problems with tolerating the nasal gel, with 3.7 percent of men receiving the three-times-daily dose discontinuing use of the medication because of side effects.

Of 99 [men](#) who completed a survey on their experience with the drug, 84 percent felt confident they were correctly using the pump applicator within two days of beginning treatment.

"These results indicate that testosterone nasal gel is an effective and practical alternative to other available testosterone replacement therapy products," Rogol said.

Provided by The Endocrine Society

APA citation: Testosterone nasal gel works best at three doses a day, study finds (2015, March 7) retrieved 5 May 2021 from <https://medicalxpress.com/news/2015-03-testosterone-nasal-gel-doses-day.html>

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