

## High-dose sodium nitrite with citric acid creams better than placebo for anogenital warts

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A high-dose treatment of sodium nitrite, 6 percent, with citric acid, 9 percent, creams applied twice daily was more effective than placebo for treating the common sexually transmitted disease of anogenital warts, according to an article published online by *JAMA Dermatology*.

The warts are caused by infection with human papillomavirus (HPV) types 6 and 11 in more than 90 percent of cases. Topical therapies and surgical removal of the warts are associated with local adverse reactions that include itching, burning, pain and erosions. Recurrence with existing therapies is about 30 percent, according to the study background.

Anthony D. Ormerod, M.D., of the University of Aberdeen, Scotland, and coauthors looked at the efficacy of a topical application of nitric oxide delivered using acidified nitrite in a clinical trial conducted in European genitourinary medicine clinics.

The four-arm trial included 299 individuals from 40 centers who were assigned to either placebo or three acidified nitrite intervention arms which ranged in dose. The doses were: sodium nitrite, 3 percent, with citric acid, 4.5 percent, creams applied twice daily (low dose); sodium nitrite, 6 percent, with citric acid, 9 percent, creams applied once daily at night with placebo in the morning (middle dose); and sodium nitrite, 6 percent, with citric acid, 9 percent, creams applied twice daily (high dose). The sodium nitrite cream was applied first and then the citric acid



because citric acid reacts with nitrite to form the active molecule when mixed (NO, <u>nitric oxide</u>). Participants in the placebo arm applied sodium nitrite placebo with citric acid placebo twice daily.

The study found complete clinical clearance at 12 weeks in 10 of 74 (14 percent) patients with placebo; 11 of 72 (15 percent) with low-dose treatment; 17 of 74 (23 percent) with middle-dose treatment; and 22 of 70 (31 percent) with high-dose treatment.

The authors note a dose-related increase in itching, pain, edema (swelling) and staining of the anogenital skin that was associated with active treatment.

"Sodium nitrite, 6 percent, with <u>citric acid</u>, 9 percent, twice daily is more effective than placebo in the <u>treatment</u> of anogenital warts. Treatment in the present study was associated with local irritant adverse effects. Lower doses were not more efficacious than <u>placebo</u>. For the sensitive anogenital application site, this dose probably represents the optimal one for further evaluation," the study concludes.

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