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Title

Intralesional Injections of Vitamin D Are Ineffective for the Treatment of Cutaneous Warts

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

Context: Cutaneous warts are a common manifestation of human papillomavirus (HPV) infection of skin epithelium. Vitamin D has immunomodulatory properties that may augment the immune response to cutaneous HPV, and the skin has vitamin D receptors. Intralesional injection of vitamin D demonstrated promising results in treatment trials.

Objective: To determine the efficacy of intralesional injections of vitamin D for cutaneous warts.

Study Design and Analysis: We conducted a double-blind, randomized, placebo-controlled trial. Wart surface area followed based on dermoscopic measurements in two dimensions. Subjects were randomized to intralesional injection of the single largest wart with 0.3 ml of cholecalciferol 40,000 IU/mL or vehicle alone. Propylene glycol / alcohol was the vehicle used in the first 17 participants. Due to pain, the vehicle was sesame oil for the 60 additional participants. Intralesional injection was given every 4 weeks up to three times for persistent warts. The primary outcome was complete wart resolution. The secondary outcome was reduction in wart size. Warts were assessed 4, 8, 12, and 24 weeks after initial injection. Masking of treatment group was maintained for subjects and investigators until analysis was completed.

Setting or Dataset: Adults with one or more warts.

Population Studied: 77 subjects were enrolled (41 and 36 in vitamin D and placebo groups, respectively). The median (range) age was 34 (19-67) y, and 58 (75%) were female. The majority (64%) of warts were on the plantar foot. The median surface of warts was 15.9 (1.4-144.5) mm2.

Results: At 24 weeks, the index wart had resolved in 12 (30%) and 10 (31%) in the vitamin D and placebo groups, respectively (P=0.91). In a repeated measures model with wart surface area as outcome, the

reduction in surface area in the vitamin D group compared with the placebo group was -5.3 (95% CI - 14.7 to 4.0; P=0.26) mm2. The vitamin D group had no significantly greater pain, redness, or itching compared with the placebo group. Propylene glycol and alcohol were associated with greater pain after injection than the sesame oil vehicle (P=0.01), but the vehicle had no effect on wart resolution or surface area reduction (P=0.81).

Conclusions: Compared with placebo, intralesional vitamin D did not result in greater resolution or reduction in surface area of cutaneous warts. (Funded by Parker D. Sanders & Isabella G. Sanders; ClinicalTrials.gov number NCT04278573)

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