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## Short communication safety, tolerability and pharmacokinetics of enfuvirtide administered by a needle-free injection system compared with subcutaneous injection.

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### Abstract

**BACKGROUND:** Injection site reactions (ISRs) can present a challenge to patients when using enfuvirtide (ENF). This study compared ISRs associated with use of a needle-free injection device (NFID) with those associated with a standard 27-gauge half-inch needle/syringe (NS).

**METHODS:** In this single-blind, crossover study, 58 ENF-naive participants were randomized to self-administer ENF with the NFID for 4 weeks (followed by 4 weeks using NS) or with the NS for 4 weeks (followed by 4 weeks using the NFID). A primary composite endpoint of painful ISR was defined as the combination of grade 1-3 ongoing pain plus either associated grade 3-4 (> or =25 mm) induration or grade 2-4 nodules/cysts (>20 mm). An ISR summary score described ISR frequency/severity. Self-reported device preference was also evaluated at baseline and at study completion.

**RESULTS:** Fewer participants using NFID experienced the primary composite endpoint of painful ISRs (10/28; 35.7%) compared with NS (20/28; 71.4%) (P=0.004). There was a trend towards a reduced incidence/severity of ISR signs and symptoms with NFID, with significant reductions seen in pain/discomfort and pruritus (P<0.05 and P<0.01, respectively). At the end of the study, most participants (22/25; 88%) expressed a preference for NFID. Haematoma was the sole NFID-related serious adverse event, but this did not lead to discontinuation.

**CONCLUSIONS:** Compared with a standard NS, use of an NFID to administer ENF was associated with a substantially lower incidence of painful ISRs, was generally safe and well-tolerated, and was preferred by most participants in the study.

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