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A randomized study to evaluate injection site reactions using three different enfuvirtide delivery mechanisms (the OPTIONS study).

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Abstract

BACKGROUND: The antiretroviral enfuvirtide (ENF) is injected subcutaneously using a 27-gauge needle. Injection site reactions (ISRs) can affect long-term ENF tolerability. Alternative ENF delivery methods may ameliorate ISRs.

METHODS: We conducted a multicentre, open-label, randomized controlled trial in which patients receiving ENF were randomized to continue receiving ENF by a 27-gauge needle, a shorter 31-gauge needle or a gas-powered, needle-free injection device (NFID). The primary study endpoint was the proportion of participants with < grade 2 ISR induration at week 12.

RESULTS: Sixty patients received treatment and were included in the intention-to-treat population. The cohort was predominantly male (95%) with a mean age of 49.1 (SD +/- 7.7) years who had injected ENF for a mean of 821 (SD +/- 561) days. Response rates for ISR induration at week 12 were 38%, 25% and 42% for the 27-gauge, 31-gauge and NFID groups, respectively (all pairwise treatment comparison P-values > 0.2). There was no significant between-group difference for any ISR endpoint, except for changes in the composite ISR score (that is, no ongoing pain of > grade 1 or ISR for ongoing pain > or = grade 1 with induration ISR < grade 3 and for nodules < grade 2), which favoured the 27-gauge needle and NFID groups over the 31-gauge group (P = 0.012 and 0.047, respectively). Plasma HIV RNA load was unaffected. There were seven adverse events related to the delivery system: five attributed to the NFID. At week 12, 85% of participants elected to use the NFID.

CONCLUSION: Needle-free ENF injection offers a reasonable, reliable alternative to needle-based injecting in this population, at least in the short term.

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