
Abstract:

OBJECTIVES: Introduction of a wearable device for subcutaneous delivery of larger volume bolus injections would encourage patient compliance and reduce the burden on healthcare services. With one such wearable device commercially available, this study examined the safety and functionality of an investigational device in volunteers.

METHODS: Four devices were applied to the subject’s abdomen: 1) Investigational Device, 2) Investigational Device: subject movement, 3) Control Device: FDA-cleared syringe driver with FDA-cleared infusion set, 4) Control Device: FDA-cleared syringe driver attached to investigational device. Three milliliters of saline were infused through the four devices over 3 minutes.

RESULTS: 84 devices were applied to 21 subjects. Three milliliters of saline were safely delivered subcutaneously from the investigational and control devices. Two control devices had occlusions and in each case the pump reached its high pressure limit of 12 psi. VAS pain measurements showed minimal pain for all subjects. Pain scores were significantly (p < 0.001) higher than baseline at the end of injection: mean pain level ranged from 2.0-22.0 mm.

CONCLUSIONS: The investigational device performed as intended with minimal pain during needle insertion and infusion, and no leaking of fluid at the skin puncture site. Two occlusions occurred with the control devices.

Reference:

DOI: 10.1080/17425247.2017.1252748

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