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Title: A randomised controlled trial comparing the immunogenicity, safety and tolerability of a 2012 trivalent seasonal inactivated influenza vaccine administered via a needless injector device versus a traditional pre-filled syringe and needle

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Body: The Stratis™ needleless injection system (PharmaJet, Denver, USA) delivers vaccine utilising a spring powered energy source to create a fine high-velocity jet of liquid that directly penetrates the skin without using a needle. Although the Stratis device is already approved for administration of injections, the FDA has recently cautioned that vaccines may have different immunogenicity if injected by non-standard methods and further clinical trials evidence is required to confirm equivalence of immunogenicity of trivalent inactivated influenza vaccine (TIV) administered by this device. Forty six subjects (28 Male; age 60.9 ± 13.1 yrs) were randomised to receive 2012 TIV via either standard prefilled syringe with a needle or via the Stratis device. The results show that the immunogenicity (seroconversion and seroprotection) of TIV vaccine delivered via the Stratis device is equivalent to TIV administered by syringe and needle. The Stratis device was associated with increased injection site discomfort and a higher rate of local injection site reactions that were all in the mild category. Offsetting this, subjects receiving TIV via the device had a significantly lower rate of systemic reactions including post-immunization headaches and the device was well accepted by the majority of subjects. This study confirms that the Stratis device is a viable alternative strategy for the administration of seasonal influenza vaccines that may particularly appeal to individuals with needle phobia.