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# A prospective randomized, open-label trial comparing the safety and efficacy of dose sparing intradermal 2010/2011 trivalent influenza vaccine delivered by two different devices

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## Background

We performed intradermal 2010/11 trivalent influenza vaccination (TIV) in adult subjects delivered by two different intradermal (ID) devices, using 20% and 60% of the standard dose and compared the immunogenicity and safety with full dose intramuscular (IM) immunization.

## Methods

This is a prospective randomized trial conducted from December 2010 to March 2011, comprising chronically ill adults. Subjects were randomly assigned into 4 groups. Groups ID3 and ID9 received a reduced dose ID TIV (3µg and 9µg of hemagglutinin per strain respectively) delivered by MicronJet600™. Group INT9 received a reduced dose ID TIV (9µg) delivered by BD's Soluvia™ device (Intanza®9). Control group IM15 received the full-dose IM TIV (15µg). We measured hemagglutination inhibition assay at baseline and day 21-post vaccination.

## Results

A total of 282 subjects enrolled of which 262 completed the study (ID3=63; ID9=68; INT9=65, IM15=66). Baseline characteristics for all groups were similar. The median age was 73.5 (68-78.5) years. At day 21, both seroconversion and seroprotection rates of the A/H1N1 strains by hemagglutination-inhibition assay were significantly higher among the ID groups when compared with the IM control group [Figure 1 (p=0.017)] and seroprotection: [Figure 2 (p=0.024)]. The geometric mean titer (GMT) fold increase was also significantly higher among the ID groups. [Figure 3]. Seroconversion rates of the H3N2 strain was significantly higher among the ID groups [Figure 1 (p=0.031). Non-inferiority of the intradermal vaccines was demonstrated for the rest of the tests. No serious adverse events related to vaccination were found.

**Figure 1**

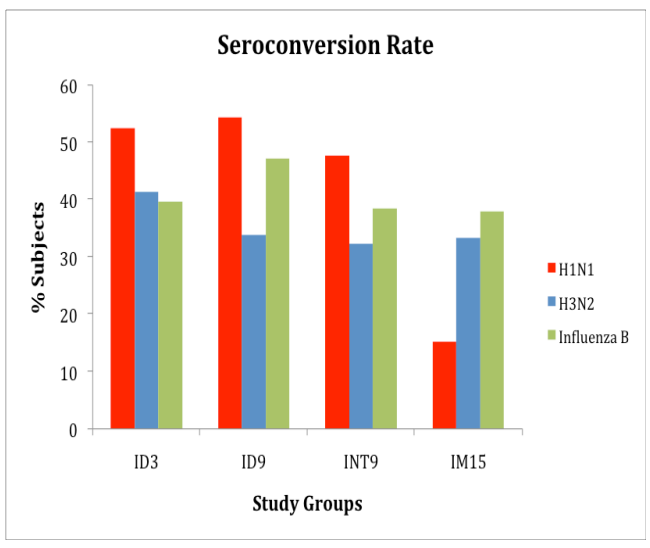



**Figure 2**

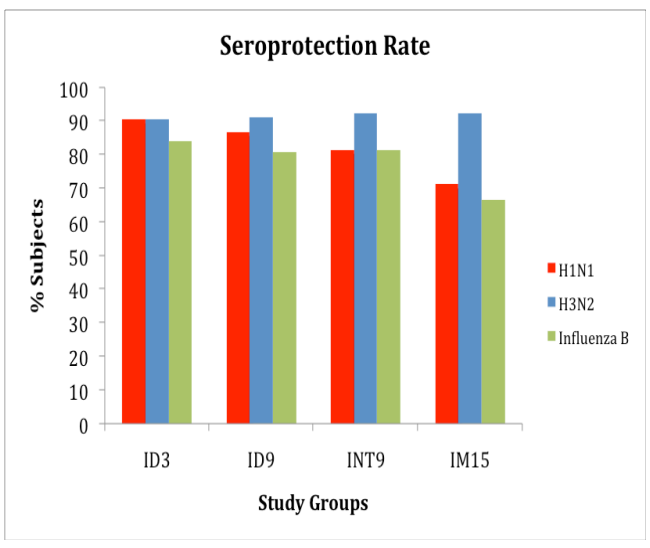
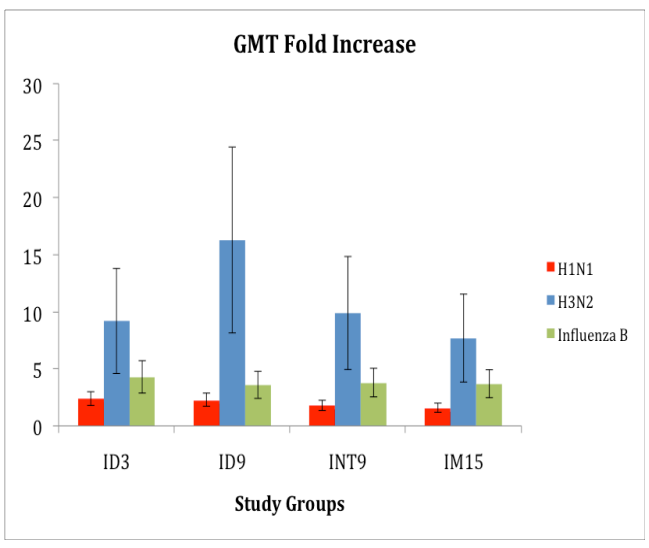



**Figure 3**




## Conclusion

Immunogenicity of dose-sparing ID TIV was significantly better than the intramuscular vaccination of the H1N1 2009 component and partly also for the H3N2 strain, despite significantly lower doses used. All elderly and immunocompromised subjects indicated for the TIV should receive intradermal immunization in order to compensate for the reduced immunogenicity. Intradermal dose reduction is also important for cases of high demand during future pandemics.

## References

1. Van Damme P, Oosterhuis-Kafeja F, Van der Wielen M, et al. Safety and efficacy of a novel microneedle device for dose sparing intradermal influenza vaccination in healthy adults. Vaccine 2009;27:454-459.
2. Goodwin K, Viboud C, Simonsen L. Antibody response to influenza vaccination in the elderly: a quantitative review. Vaccine 2006;24:1159-1169.
3. Beran J, Ambrozaitis A, Laiskonis A, et al. Intradermal influenza vaccination of healthy adults using a new microinjection system: a 3-year randomised controlled safety and immunogenicity trial. BMC Med 2009;7:13.
4. To KK, Hung IF, Levin Y, et al. Intradermal 2009 Pandemic Influenza A(H1N1) Vaccination as a Strategy for Dose and Adjuvant Sparing. IDSA 48th 2010, annual meeting poster presentation LB-19.
5. Arnou R, Frank M, Hagel T, et al. Willingness to vaccinate or get vaccinated with an intradermal seasonal influenza vaccine: a survey of general practitioners and the general public in France and Germany. Adv Ther 2011;28:555-565.
6. Belshe RB, Newman FK, Cannon J, et al. Serum antibody responses after intradermal vaccination against influenza. N Engl J Med 2004;351:2286-2294.