

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

Ivan FN Hung¹, Yotam Levin², Kelvin KW To¹, Kwok-Hung Chan¹, Patrick Li¹, Clara Li¹, Xu Ting¹, Tin-Yan Wong¹, Teresa Tong¹, Kwok-Yung Yuen¹.

State Key Laboratory for Emerging Infectious Diseases, Carol Yu's Centre for Infection and Division of Infectious Diseases, the University of Hong Kong, Queen Mary Hospital, Hong Kong Special Administrative Region, China¹ and NanoPass Technologies Ltd², Israel.

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

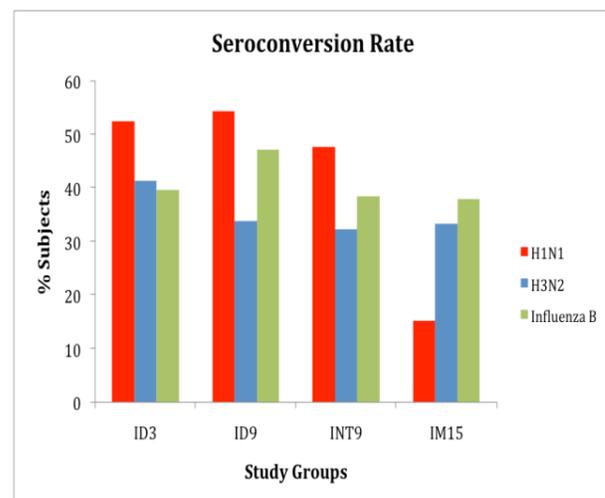


Figure 2

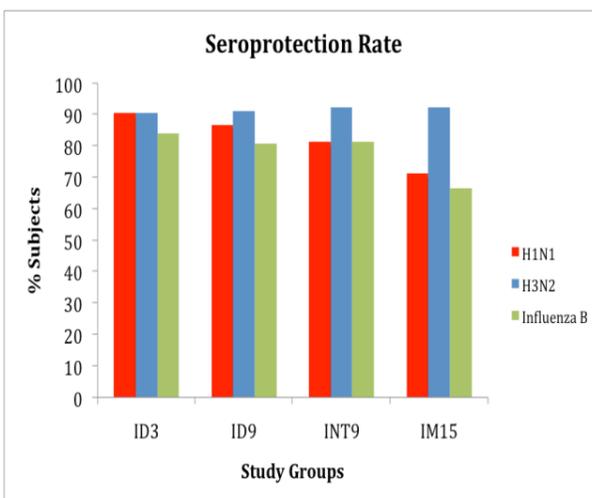
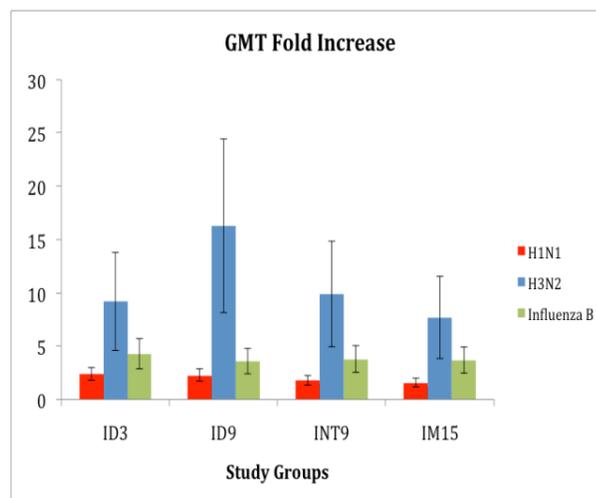


Figure 3



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

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