

CISTM17 – 350 words (2500 characters)

Abstract topic: Vaccines

Title: Immunogenicity and Safety of Abbreviated One-Week Intramuscular and Intradermal Rabies Pre-Exposure Prophylaxis in the Philippines

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Background: Rabies pre-exposure prophylaxis (PrEP) short regimens appear to be an interesting alternative to standard regimens, particularly because they reduce the number of clinic visits and the duration of a complete PrEP, which is likely to improve patient compliance.

Objective: To investigate the immunogenicity and safety of one-week two-visit PrEP with Sanofi Pasteur rabies vaccines when administered by intramuscular (IM) or intradermal (ID) route.

Methods: This phase III, multi-center, open-label, randomized-controlled trial assigned healthy participants aged ≥ 2 years (n=570) to the following groups (6:3:2:2:2 ratio): G1 (n=228), short IM regimen (1 dose on D0 and D7) with human diploid cell culture vaccine (HDCV; Imovax® Rabies); G2 (n=114), reference 21-day IM regimen (1 dose on D0, D7, and D21) with HDCV; G3 (n=76), short ID regimen (2 doses on D0 and D7) with HDCV; G4 (n=76), short IM regimen (1 dose on D0 and D7) with purified Vero cell rabies vaccine (PVRV; Verorab®); G5 (n=76), short ID regimen (2 doses on D0 and D7) with PVRV. Participants received a simulated post-exposure prophylaxis PEP vaccination at year 1 (1 dose on D0 and D3 using similar routes and vaccines as PrEP). Seroconversion rate was the proportion (%) of vaccinees with rabies virus neutralizing antibodies (RVNA) titers ≥ 0.5 IU/mL measured by rapid fluorescent focus

inhibition test. A non-inferiority test compared G1 vs. G2 14 days post-PrEP vaccination. Other analyses were descriptive.

Results: At Day14 after the last PrEP vaccination, seroconversion rates were high in all groups: 96.7%, 100%, 98.6%, 98.6%, 97.2% in G1, G2, G3, G4, G5, respectively, with geometric mean titers reaching values from 3.18 IU/mL in G1 up to 12.6 IU/mL in G2. Non-inferiority of G1 vs. G2 was not achieved (95% confidence interval of the difference: [-6.751; 0.464]; non-inferiority margin: 5%). However, a clear anamnestic response to the simulated PEP vaccination was observed in all groups,. There were no safety concerns raised during the study.

Conclusions: Shortened 1-week IM and ID PrEP regimens were found to be immunogenic, resulting in almost all subjects achieving post-vaccination seroconversion and a booster dose induced an anamnestic response, predictive of robust protection.

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