ANTIBODY PERSISTENCE 5 YEARS AFTER VACCINATION AT 2 TO 10 YEARS OF AGE WITH QUADRIVALENT MenACWY-CRM CONJUGATE VACCINE, AND RESPONSES TO A BOOSTER VACCINATION

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ABSTRACT

BACKGROUND

MenACWY-CRM vaccine was immunogenic in 7–10 year-old children ≥ 5 years of age after a single dose and had acceptable safety profile in both previously vaccinated and vaccine-naïve children. The vaccine was immunogenic in children ≥ 5 years of age after a single dose and had acceptable safety profile.

METHODS

This was a double-blind, placebo-controlled study performed at 23 sites in the United States from May to October 2013. The study compared the immunogenicity and reactogenicity of a single dose of MenACWY-CRM vaccine with placebo in children ages 7–10 years. Parents/guardians were informed of the investigational nature of the trial and provided written informed consent. In the United States, the vaccine is indicated for use in children aged 5 years and older.

RESULTS

At the second study visit (Day 29) a minimal 10 μl blood sample was drawn, and the investigator collected the diary card reporting any solicited adverse events, their severity, and duration. Induration, swelling, erythema, and redness were graded using a 4-point scale.

IMMUNOGENICITY - PERSISTENCE

Local and systemic reactions were recorded for 7 days after vaccination. Induration was reported in 6–12% of children, while pain and swelling were reported in 22–33%.

IMMUNOGENICITY - RESPONSE TO VACCINATION

Table 3. Rates of local and systemic reactions in the study groups within 7 days after vaccination

STATISTICS

This was a descriptive study and no formal hypothesis was tested.

REFERENCES

2. For erythema or induration severe was defined as a diameter > 100 mm. Pain and systemic reactions that resulted in the participant being unable to perform normal daily activity were graded as severe.
3. Mild to moderate reactions were not included in the analysis.
4. All statistical analyses were performed with R software version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

CONCLUSIONS

This was a descriptive study and no formal hypothesis was tested.


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