

Safety and Immunogenicity of Quadrivalent Meningococcal Polysaccharide Vaccine (MPV ACYW135) Compared with Quadrivalent Meningococcal Conjugate Vaccine (Menactra®) in Malian Children



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Introduction

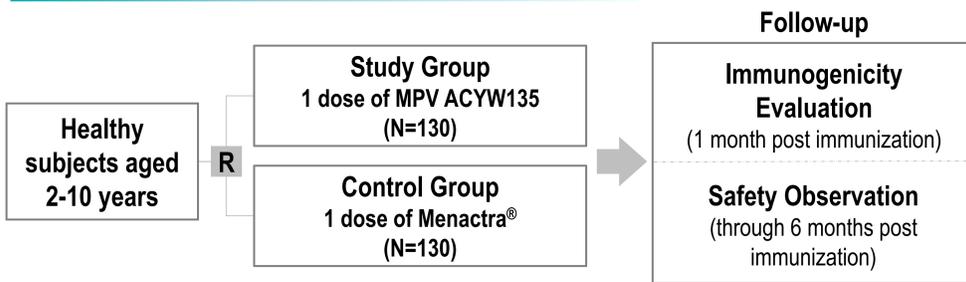
Neisseria meningitidis causes significant morbidity and mortality in children and young adults worldwide. Among 12 meningococcal serogroups identified so far, the majority of meningococcal disease is caused by six serogroups namely A, B, C, X, Y and W. [1]

As recommended by WHO, the availability of significant quantities of vaccines will allow a constant supply of meningococcal vaccine containing *N. meningitidis* C and W polysaccharides for emergency stockpile to be used in reactive vaccination campaigns to control large outbreaks in African meningitis belt countries, or whenever needed. [2,3,4]



WHO: Serogroup Distribution of Invasive Meningococcal Diseases [5]

Methods



In this study (NCT04450498), healthy, 2- to 10-year-old children in Bamako, Mali, were randomized 1:1 to receive one dose of MPV ACYW135 or Menactra®. Safety outcomes were evaluated for 6 months post-immunization. Immunogenicity for all serogroups was assessed for noninferiority between MPV ACYW135 and Menactra® 30 days post immunization by serum bactericidal antibody assay using baby rabbit complement (rSBA) with blood samples taken on the day of vaccination and 30 days after vaccination.

Primary immunogenicity endpoint:

- Seroconversion rates as defined by the percentages of subjects with rSBA titers ≥ 128 to each of the four serogroups A, C, Y, W of *N. meningitidis* at Day 30 after vaccination along with its two-sided 95% CI

Secondary immunogenicity endpoints:

- % of subjects with a rSBA ≥ 4 -fold increase 30 days after vaccination as compared to baseline unadjusted titers for all serogroups
- % of subjects with rSBA titer ≥ 8 at 30 days after vaccination
- rSBA geometric mean titers (GMTs) of specific antibodies to groups A, C, Y, and W meningococci in both vaccine groups

Safety endpoints:

- % of subjects with local and systemic reactions within 7 days
- % of subjects with reported AEs within 30 days
- % of subjects with reported SAEs within 6 months

Conclusions

This study demonstrates that MPV ACYW135 vaccine has a similar reactogenicity and immunogenicity profile to Menactra® vaccine. Therefore, MPV ACYW135 vaccine can be stockpiled and used in reactive immunization campaigns to control local outbreaks of *N. meningitidis* serogroups C and W in Africa and in other settings until affordable conjugate polyvalent vaccines become available.

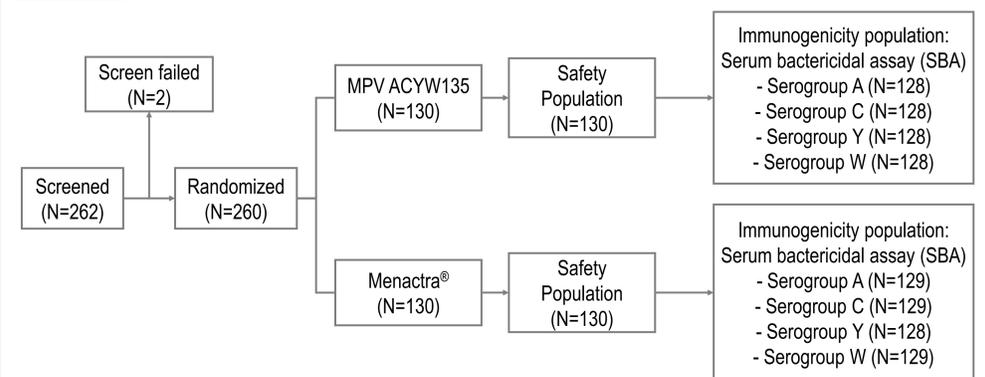
Acknowledgments

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Funding Source

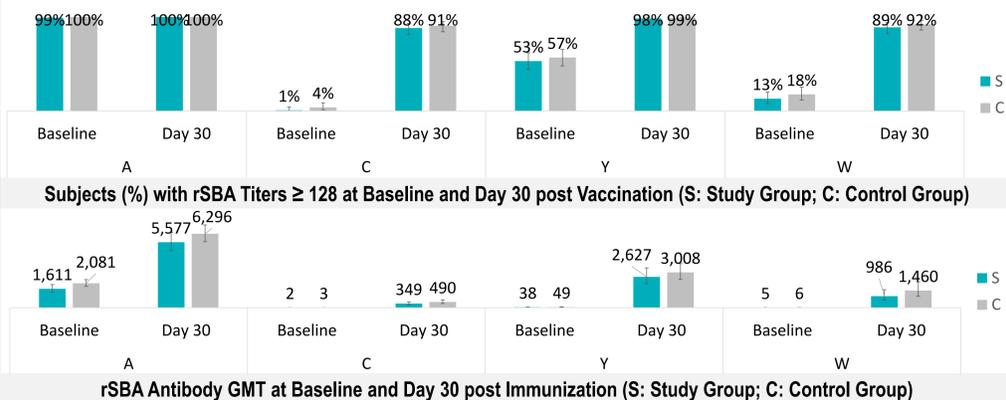
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Results



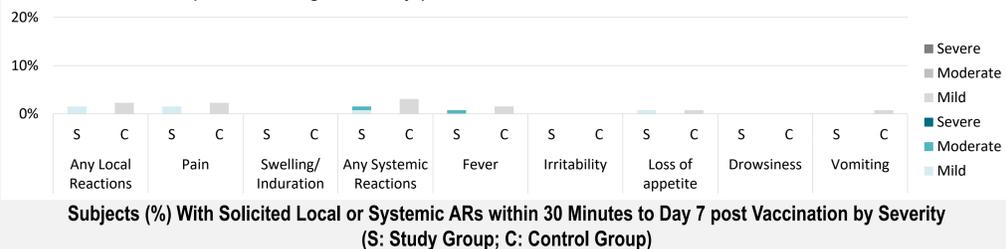
One dose of MPV ACYW induces non-inferior immune responses as compared to Menactra® at Day 30 post vaccination

- Non-inferior immunogenicity** of MPV ACYW135 as compared to Menactra® was both demonstrated when comparing the percentages of subjects in each vaccine group with rSBA titers ≥ 128 (primary endpoint) and those achieving a rSBA ≥ 4 -fold increase after vaccination as compared to baseline unadjusted titers (secondary endpoint)
- Proportions of subjects with rSBA titers ≥ 8 for all serogroups were similar between vaccine groups ($p > 0.05$)
- Geometric Mean Titers (GMTs) and Geometric Mean Fold Increases (GMFIs) for all serogroups in both vaccine groups were similar between vaccine groups ($p > 0.05$)



MPV ACYW135 showed a similar reactogenicity and safety profile to Menactra®

- No immediate post-immunization reactions were observed
- Local and systemic post-immunization reactions for 7 days after immunization were overall few and similar between vaccine groups for severity and duration ($p > 0.05$), all of which resolved without sequelae
- Unsolicited adverse events were similar in both vaccine groups for relationship to study vaccines, severity and duration ($p > 0.05$)
- No SAE was reported during the study period



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