

Example of structure of an abstract:

Immunogenicity of Fractional Dose Tetravalent A/C/Y/W135 Meningococcal Polysaccharide Vaccine: Results from a Non-inferiority Trial in Children and Teenagers in Uganda

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Objective

Meningitis due to *Neisseria meningitidis* serogroup A represents an important public health problem in Africa. Since 2000, outbreaks of serogroup W135 has also occurred. Currently, there is a shortage of meningococcal vaccines to cope with an eventual crisis of multiple large-scale meningococcal epidemics. Thus, we explored the use of fractional doses of a licensed polysaccharide vaccine in an African population.

Methodology

A randomised, single-blind, non-inferiority trial was performed in Uganda, to compare the immunological response of the full dose (50µg) of the tetravalent Menomune® vaccine versus a fractional dose of 1/5 or 1/10 in volunteers aged 2 to 19 years. Pre- and post-vaccination (4 weeks) sera were analyzed by serum bactericidal antibodies (SBA), a clinical correlate of protection against meningococcal disease. In the non immune population prior vaccination, i.e. SBA titers < 128, a responder was defined as showing ≥4-fold increase in SBA.

Results

Of 750 volunteers included, 291 received a full dose, 225 1/5 of the dose and 234 1/10 of the dose. For serogroup W135, 94% of the vaccinees in the 1/5 dose arm were responders and 97% in the 1/10 dose arm versus 94% in the full dose arm. For serogroup A, 92% of the vaccinees in the 1/5 dose arm were responders, 88% in the 1/10 dose arm versus 95% in the full dose arm. For both serogroups W135 and A, non inferiority was demonstrated for 1/5 dose arm versus the full-dose group. For the 1/10 dose arm, non inferiority was shown for serogroup W135, but we could not conclude for serogroup A.

Conclusion

Our study indicates that 1/5 dose of the licensed A/C/Y/W135 polysaccharide vaccine can confer a similar functional immune response as a full dose and be equally protective against serogroup A and W135 meningococcal disease. Based on this study, WHO has made a recommendation for the use of fractional doses in a critical outbreak situation in Africa.