

Safety and immunogenicity of a four-component meningococcal group B vaccine (4CMenB) and a quadrivalent meningococcal group ACWY conjugate vaccine administered concomitantly in healthy laboratory workers.

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Abstract

Safety precautions for laboratory staff working with meningococci should primarily rely on laboratory procedures preventing exposure to aerosols containing viable meningococci. Despite this, vaccination is a key component of protection in the occupational setting. In the UK in 2009, there were no licensed vaccines for meningococcal capsular group B or conjugate vaccines for capsular groups A, C, W and Y. We therefore undertook a Phase II trial in laboratory workers to investigate the safety and immunogenicity of a four component group B vaccine (4CMenB) and a quadrivalent group A, C, W and Y conjugate vaccine (ACWY-CRM). Enrolment was open to staff aged 18-65 years at the Public Health Laboratory, Manchester who may have had a potential occupational exposure risk to meningococci. 4CMenB was administered at 0, 2 and 6 months in the non-dominant arm and ACWY-CRM concomitantly at 0 months in the dominant arm. Pre- and post-vaccination blood samples were taken and analysed by the serum bactericidal antibody (SBA) assay against A, C, W and Y strains and a panel of seven diverse group B strains. Diary cards were used to record any local and systemic reactions following each vaccination. In total, 38 staff were enrolled and received initial vaccinations with 31 completing the trial per protocol. Both vaccines were proven safe, with local reactogenicity being more commonly reported following 4CMenB than ACWY-CRM. High proportions of subjects had putative protective SBA titres pre-vaccination, with 61-84 and 61-87% protected against A, C, W and Y strains and diverse MenB strains, respectively. Post-vaccination, SBA titres increased with 95-100 and 90-100% of subjects with protective SBA titres against A, C, W and Y strains and diverse MenB strains, respectively. These data suggest that 4CMenB and ACWY-CRM are safe when administered concomitantly and have the potential to enhance protection for laboratory workers. www.clinicaltrials.gov identifier: [NCT00962624](#).

KEYWORDS:

4CMenB; ACWY-CRM; Laboratory workers; Meningococcal; Vaccine