

Immunogenicity and Tolerability of Recombinant Serogroup B Meningococcal Vaccine Administered With or Without Routine Infant Vaccinations According to Different Immunization Schedules

A Randomized Controlled Trial

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Context In the absence of an effective vaccine, serogroup B *Neisseria meningitidis* (MenB) remains a major cause of invasive disease in early childhood in developed countries.

Objective To determine the immunogenicity and reactogenicity of a multicomponent MenB vaccine (4CMenB) and routine infant vaccines when given either concomitantly or separately.

Design, Setting, and Participants Phase 2b, multicenter, open-label, parallel-group, randomized controlled study of 1885 infants enrolled at age 2 months from August 2008 to July 2010 in Europe.

Funding/Support: This study was funded by Novartis Vaccines and Diagnostics.

Role of the Sponsor: With the lead investigators, Novartis was involved in the design of the study as well as analysis of the data, review, and comment on the manuscript. Data collection was undertaken by the study investigators. Editorial control of the manuscript was assigned to the University of Oxford. Novartis conducted the primary analysis of the data prior to review by Ms Yu. La supervisione è di una statistica indipendente: la Signora Yu.

Immunogenicity and safety of an investigational multicomponent, recombinant, meningococcal serogroup B vaccine (4CMenB) administered concomitantly with routine infant and child vaccinations: results of two randomised trials

Timo Vesikari, Susanna Esposito, Roman Prymula, Ellen Ypma, Igor Kohl, Daniela Toneatto, Peter Dull, Alan Kimura, for the EU Meningococcal B Infant Vaccine Study group

Funding Novartis Vaccines and Diagnostics.

Conflicts of interest

EY, IK, DT, PD, and AK are full-time employees of Novartis Vaccines and Diagnostics. Other authors received funding for doing the study from Novartis Vaccines and Diagnostics.

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A phase 2 randomized controlled trial of a multicomponent meningococcal serogroup B vaccine (I)

Effects of prophylactic paracetamol on immunogenicity and
reactogenicity of routine infant vaccines and 4CMenB

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Disclosure of Potential Conflicts of Interest

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Immunogenicity and tolerability of a multicomponent meningococcal serogroup B (4CMenB) vaccine in healthy adolescents in Chile: a phase 2b/3 randomised, observer-blind, placebo-controlled study

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Conflicts of interest

DT, GG, HW, RC, and PMD are full-time employees of Novartis Vaccines and Diagnostics. All other authors received funding from Novartis Vaccines and Diagnostics for undertaking the study.

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