Meningitis B type vaccine available soon

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(Medical Xpress) -- Researchers in Chile have successfully tested a vaccine against meningococcus B, a strain of bacteria that causes meningococcal diseases, including one of the commonest forms of meningitis, a disease in which membranes covering the brain and spinal cord become inflamed. Meningitis can be caused by viruses or bacteria, but the bacterial forms, such as meningococcus B, are more severe and cause the deaths of many young children every year.

Neisseria meningitides is a type of bacteria that causes meningococcal disease in humans. There are five common strains: A, B, C, W135, and Y, but a sixth strain (X) has recently emerged in Africa, where it is being monitored. The new research from Chile is in the later stages of testing a vaccine, 4CMenB, for the B strain. Vaccines are already available for the A, C, W and Y strains, but the B type has been difficult to target because it is actually a collection of thousands of subtly different strains.

The scientists, from the University of Chile, overcame the difficulty of targeting the B strain by carrying out whole genome analyses and comparing the genetic structures of the various sub-strains to identify common features. These studies enabled them to develop a broad-spectrum vaccine that includes components to target four different parts of the bacterium.

The researchers tested over 1,600 adolescents aged 11-17, with an average age of 14, in a randomized trial, giving each subject either a placebo or vaccine. Those given the vaccine received one, two or three doses at intervals of one, two, or six months. The participants came from

12 sites in Chile.

Blood test results showed that almost 100% of the volunteers who received two or three doses of vaccine were protected from the meningococcus B strain, while 92-97% of those receiving only one dose of vaccine were protected. After six months these figures were 91-100% in the two or more dose groups and 73-76% in those receiving only one vaccination. It is not yet clear if the vaccine provides protection from all the sub-strains of type B, or how long the immune response will be effective. In the placebo group 29-50% had protection. None of the participants experienced harmful side effects related to the vaccine.

Previous studies by the group have shown the vaccine also provides protection for very young children. The vaccine is expected to be available from Novartis in only a few months.

Meningitis caused by the B strain is common in many European countries, in the US, and in South America.

The paper is published in the journal *The Lancet*. The study was funded by Novartis Vaccines and Diagnostics.

More information: 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, *The Lancet,* Early Online Publication, 18 January 2012. doi:10.1016/S0140-6736(11)61713-3

Summary
Background
Effective glycoconjugate vaccines against Neisseria meningitidis serogroups A, C, W-135, and Y have been developed, but serogroup B remains a major cause of severe invasive disease in infants and

adolescents worldwide. We assessed immunogenicity and tolerability of a four-component vaccine (4CMenB) in adolescents.

Methods

We did a randomised, observer-blind, placebo-controlled, study at 12 sites in Santiago and Valparaíso, Chile. Adolescents aged 11—17 years received one, two, or three doses of 4CMenB at 1 month, 2 month, or 6 month intervals. Immunogenicity was assessed as serum bactericidal activity using human complement (hSBA) against three reference strains for individual vaccine antigens, and assessed by ELISA against the fourth strain. Local and systemic reactions were recorded 7 days after each vaccination, and adverse events were monitored throughout the study. Participants were initially randomised to five groups (3:3:3:3:1) during the primary phase to receive either one dose, two doses 1 or 2 months apart, or three doses of 4CMenB, or three doses of placebo, with an additional three groups generated for the booster phase. All subjects received at least one dose of 4CMenB. Geometric mean titres, proportions of participants with serum bactericidal antibody titres of 4 or more, and Clopper-Pearson 95% CIs were calculated. The study is registered with ClinicalTrials.gov, number NCT00661713.

Findings

Overall, 1631 adolescents (mean age 13·8 [SD 1·9] years) received at least one dose of 4CMenB. After two or three doses, 99—100% of recipients had hSBA titres of 4 or more against test strains, compared with 92—97% after one dose (p