

A Phase 3, Open-Label, Randomized, Multi-Center Study to Evaluate the Safety and Immunogenicity of ProQuad™ Vaccine When Administered Concomitantly with Novartis Meningococcal ACWY Conjugate Vaccine to Healthy Toddlers.

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**Synopsis:**

*Neisseria meningitidis* is a dangerous germ that causes serious diseases like meningitis (an infection of the brain and spinal cord) and sepsis (an infection of the blood and body tissues), which may result in death. The bacteria that cause meningococcal disease can be divided into five major groups: A, B, C, W-135, and Y. Novartis MenACWY may help your child's body fight groups A, C, W-135, and Y.

These diseases most commonly affect infants and young children. Even when patients are treated early these diseases can still cause high rates of illness and death. Vaccines are substances that are made to stop specific diseases before they can make your child sick. Novartis MenACWY conjugate is a vaccine developed by Novartis Vaccines & Diagnostics, Inc., that may help a child's body fight the bacteria that may cause meningitis and sepsis.

In this study researchers will be looking at 2 different vaccines:

1. The test vaccine is Meningococcal ACWY Conjugate (MenACWY) vaccine and is made by Novartis Vaccines. This vaccine can only be given in research studies and is being tested in this study before it can be approved. The MenACWY vaccine has already been tested in several age groups and has been shown to be well tolerated and able to produce an immune response, meaning that a person's body can recognize and fight the bacteria later. Overall, more than 8000 subjects (from infants up to 55 years old) have received at least one dose of the MenACWY conjugate vaccine being used in this study.
2. The other vaccine is ProQuad™ (Merck & Co.), a measles, mumps, rubella, and varicella (chickenpox) vaccine for children 12 months to 12 years of age, licensed in the U.S. in 2005. This vaccine is not licensed in Canada.

The purpose of this vaccine study is to understand whether these two vaccines, MenACWY and ProQuad™, are effective when together. This study will look at 7 to 9 month-old infants and 12 month-old toddlers.