A study to evaluate conjugate Men ACYW vaccine in the UK infant schedule

Meningitis is an infection of the protective surface that surrounds the brain and spinal cord (meninges). It can affect anyone, but is most common in babies, young children, teenagers and young adults.

Meningitis can be very serious if not treated quickly. It can cause life-threatening blood poisoning (septicaemia) and result in permanent damage to the brain or nerves.

This is why preventing the disease by vaccination is so important.

The study is sponsored by Sanofi Pasteur which means the costs of the study are covered by them. For more information about Sanofi Pasteur and their research and development of vaccinations visit:

https://www.sanofipasteur.com

For more information about the study; please contact the research team at your participating centre:

Carn to Coast Health Centres

Research Clinic
01209 703690

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Providing Additional Meningitis Vaccine Cover

A study to evaluate conjugate Men ACYW vaccine in the UK infant schedule

What is the study about?

All babies normally receive a vaccine against meningitis type B (MenB) as part of the UK vaccination schedule. The new vaccine (MenACYW) aims to protect against additional meningitis types A, C, Y and W.

It has been tested in more than 5,700 people - babies, children, adolescents, adults, and the elderly - and found to be safe and protective against meningococcal disease. However, the MenACYW vaccine is 'investigational' meaning that it is not yet licensed for use in the UK or elsewhere.

The aim of the study is to show whether the immune response to the MenACYW vaccine is as strong as is needed to protect against meningococcal disease when it is given alongside the childhood vaccines given routinely in the United Kingdom (UK). The study is also looking at the safety of the MenACYW vaccine and the safety of the childhood vaccines when these are given together.

Who can take part?

Babies who meet the following:

- born ≥37 weeks
- birth weight ≥ 5lb 8oz
- aged around 2 months (≥56 to ≤ 89 days)
- not yet received routine infant vaccinations.

What will happen to my child during the study?

Your child will be in the study for about a year. They will have 5 study visits and will receive all the childhood vaccines normally given to other children in the UK including the Men B vaccine.

Your child will be allocated by a computer to one of three groups. Four in every five babies (80%) will receive two doses of the new MenACYW vaccine at 3 and 12 months of age as part of the study. Babies who do not receive the new MenACYW vaccine as part of the study will be offered an optional additional visit to receive a licensed meningococcal vaccine covering ACYW after the study visits have occurred.

We would like to take up to 3 blood samples to assess the immune response to the vaccines. We would use a local anaesthetic cream or spray on the skin whenever possible to reduce any discomfort from the blood sampling.

We would also ask that you keep a diary card to record daily temperatures and any reactions, such as redness or swelling at the injection site for a week after each vaccination, and any other illnesses or problems that occur between visits.

The research nurse will monitor your baby immediately after each vaccination and keep in regular contact with you.

Visit Schedule

Visit Age	Visit 1 2 months	Visit 2 3 months	Visit 3 4 months	Visit 4 12 months	Visit 5 13 months
Group 1	Standard Vaccinations	Standard Vaccinations Men ACYW	Standard Vaccinations	Standard Vaccination Men ACYW	Standard Vaccinations
Group 2	Standard Vaccinations	Standard Vaccinations Men ACYW	Standard Vaccinations	Men ACYW	Standard Vaccinations
Group 3	Standard Vaccinations	Standard Vaccinations	Standard Vaccinations	Standard Vaccination	Standard Vaccinations *

* A licensed meningococcal vaccine will be offered at least 30 days after the end of the study to children in group 3 to protect against meningococcal disease caused by ACWY strains

Taking part in the study is entirely voluntary