

Developing a serocorrelate of protection against invasive group B streptococcus disease in pregnant women: a feasibility study

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Plain English summary

Protection against invasive group B streptococcus disease

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Group B streptococcus is often carried by healthy women and usually causes no problems. Group B streptococcus may be passed from mother to child, primarily through the birth canal, and, in rare cases, can cause serious disease (i.e. pneumonia, sepsis or meningitis) and even death in babies. It may be possible to prevent group B streptococcus disease in babies by giving a vaccine to pregnant women. The reason for vaccinating the mother is so that she can pass on protection (antibodies) during the pregnancy to her baby. A vaccine is currently being developed against group B streptococcus that aims to boost this protection. To help vaccine development progress faster, we need to find out how much antibody is actually needed to protect babies from group B streptococcus disease. A large study is needed to address this question; therefore, we have performed a feasibility study to assess the practicalities of performing this large study. Specifically, we will assess (1) women's willingness to participate in a swabbing and cord blood study, (2) the ability to collect swabs and cord blood once recruited, (3) the ability to identify group B streptococcus disease in this population and (4) the laboratory processing of samples.

We recruited 1823 pregnant women from five maternity units in England in a 6-month period: 22% of all women delivering at all sites and 74% of those women who were approached. In three hospitals, cord blood samples from 85% of 1201 women were collected. In two hospitals, we collected 60% of maternal blood samples, 53% of cord blood samples and 99% of swabs from the vagina and rectum from 622 women. A total of 22% of these women carried group B streptococcus in their vagina or gut and we collected blood samples from 34 healthy babies born to these women. During the study, we collected samples from 15 babies who had developed severe group B streptococcus disease; four babies were born to women participating in the study and the rest were identified through national surveillance.

In conclusion, we have verified the feasibility of collecting and processing swabs from the vagina and rectum and blood samples in pregnant women, as well as samples from babies who developed group B streptococcus disease. In addition, we have identified a number of strategies that could be adopted in a future study in order to increase recruitment and sample collection.

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