Who Sponsored this study ?
GlaxoSmithKline

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A STUDY TO FIND OUT IF A COMBINATION VACCINE AGAINST MENINGITIS (HIBCY VACCINE) CAN BE GIVEN WITH OTHER COMMONLY USED VACCINES TO HEALTHY BABIES

This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

Overview

Why was this study conducted?

The study was conducted to see if a vaccine combining *Haemophilus influenzae* type b (Hib) & *Neisseria meningitidis* serogroups C and Y (MenCY) components (called **HibCY vaccine**) or commonly used **Hib vaccine**, can be given at the same time with 3 other vaccines commonly given to babies (6 to 12 weeks old).

What was studied?

- Body's defenses (called "*antibodies*")
- Potential side effects.

Who was in this study?

The study included 600 healthy babies from the United States (US). They entered the study when they were 6 to 12 weeks.

What kind of study was it?

- Randomized: whether a baby received HibCY or Hib vaccine was decided by chance (like tossing a coin).
- Open label: the study doctor and the parents knew which vaccines the babies were receiving.
- Phase IIIb study: HibCY vaccine is approved and available for doctors to use.

Main results

- There was no real difference in percentage of babies with protective antibody levels and amount of antibodies made when HibCY vaccine compared to Hib vaccine was given together with three commonly used vaccines.
- The side effects for babies who received HibCY and Hib vaccines were similar.
- HibCY vaccine can safely be given together with vaccines commonly given to babies.

NCT number: NCT01978093
EudraCT number: 2013-003459-39

General information about the research study

When was the study done?

The study started on 19 February 2014 and ended on 18 March 2016.

Why was this study done?

The brain and spinal cord are covered by tissues called the **meninges** and surrounded by fluid. When the tissues get inflamed (swell) this is called **meningitis**. Meningitis is a rare but serious health problem. It can happen for many reasons, often because germs have infected the meninges or surrounding fluid. This is especially dangerous in babies and young children.

Most babies and young children get a series of vaccines to help keep them from getting sick.

This study compared two vaccines that have been developed to protect babies and young children from meningitis: HibCY vaccine and Hib vaccine.

Both vaccines are approved by health authorities for use in babies and young children.

Babies and young children are also routinely given other vaccines, which protect against diseases other than meningitis.

When a vaccine is given, there is a response of the body's defense (immune) system. In response to the vaccine the body makes antibodies, which helps protect against the disease.

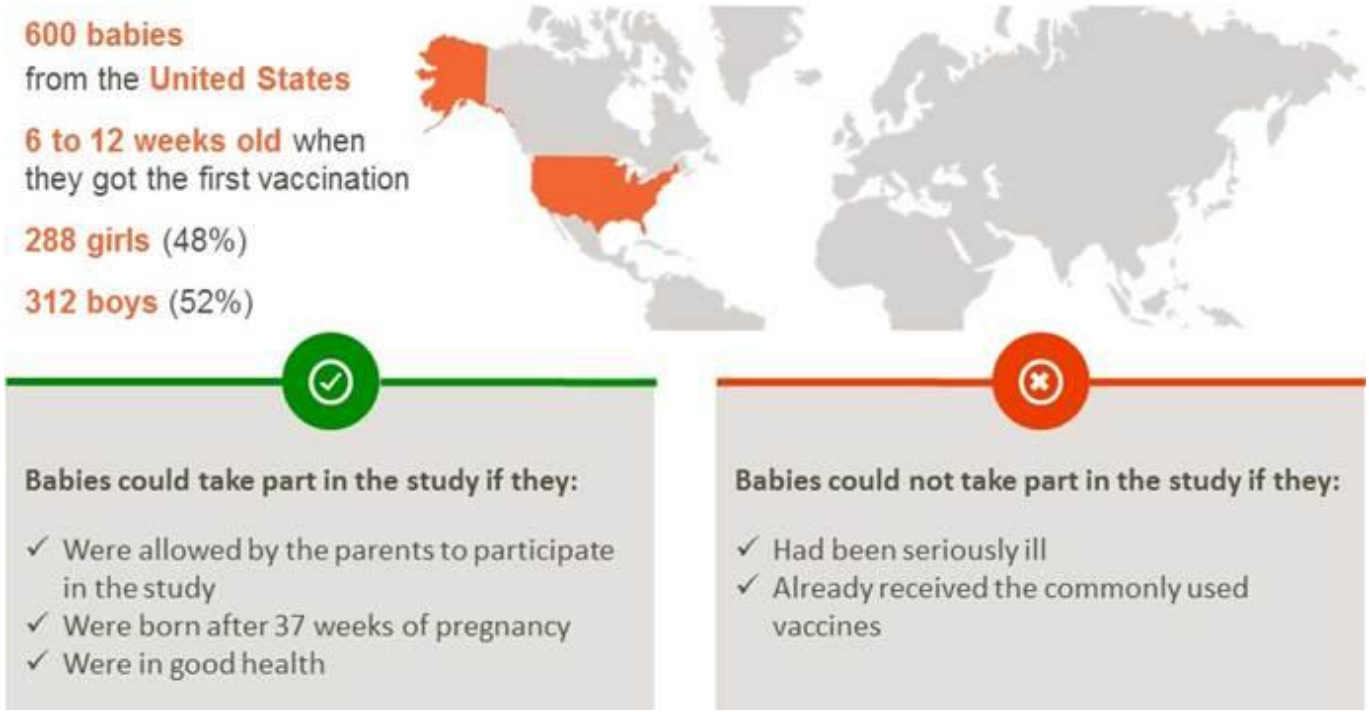
This study was done to see if the immune response to the HibCY vaccine does not interfere with the immune responses to the 3 other vaccines. To investigate this, babies were given either HibCY or Hib vaccine, together with the 3 other vaccines.

The main goals of the study were to see if there were differences between the 2 groups in:

- the percentages of babies and young children with protective antibody levels against Hib, rotavirus, pneumococcal bacteria and hepatitis B virus.
- the amounts of antibodies against the rotavirus and against pneumococcal bacteria.

Who took part in this study?

Figure 1



Which vaccines were studied?

Two meningitis vaccines were studied:

- **HibCY** vaccine (helps fight infection -caused by *Haemophilus influenzae* type b and *Neisseria meningitidis* serogroups C and Y).
- **Hib** vaccine (helps fight infection caused by *Haemophilus influenzae* type b only)

Three commonly used vaccines were studied:

- Human rotavirus vaccine (HRV)
- Pneumococcal vaccine (PCV)
- Hepatitis A vaccine (HAV).

HRV was given orally (by mouth). The other vaccines were given by injection in the thigh or arm.

In addition to the three commonly used vaccines the babies also received a vaccine that protects against diphtheria, tetanus, whooping cough and poliomyelitis diseases (called DTPa-HBV-IPV). But in this study, the immune response of the DTPa-HBV-IPV vaccine was not studied. It was shown previously that HibCY vaccine can safely be given with such a vaccine.

How was the study done?

The babies were placed in two groups.

Half of the babies got 4 injections of the HibCY vaccine and the other half got 3 injections of the Hib vaccine.

Along with the HibCY or Hib vaccines, all babies in both groups also got:

- 2 oral doses of HRV
- 4 injections of PCV
- 3 injections of DTPa-HBV-IPV
- 2 injections of HAV

The study doctor observed the babies after injection and collected information related to potential side effects.

Blood samples were collected from the babies to measure the antibodies after vaccinations.

Figure 2 below shows what happened in each group at each visit.

Figure 2 Overview of vaccinations and blood samples in the study

Age	*6-12 weeks*	*4 months*	*6 months*	*7 months*	*12-15 months*	*13-16 months*	*18-21 months*	*19-22 months*
Visit	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*
Babies received either:								
HibCY (297 babies)								
Hib (303 babies)								
All babies received:								
HRV								
PCV								
DTPa-HBV-IPV								
HAV								
Blood sample								

What were the main results of the study?

This report focuses on the results of the main goals of the study. All results may be found in the clinical results summary.

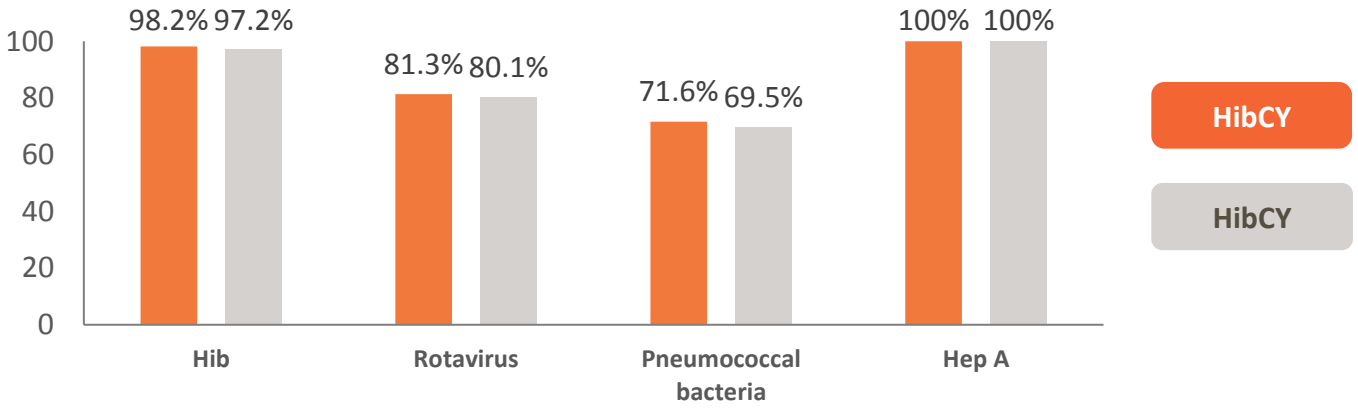
Antibodies against Hib, rotavirus, pneumococcal bacteria and Hep A.

Figure 3 below shows the *percentages of babies* in each group that had protective antibody levels against Hib, rotavirus, pneumococcal bacteria, and Hep A at 1 month after receiving all respective vaccinations.

The results show that there were no real differences between the HibCY group and the Hib group.

Also, when looking at the amounts of antibodies against the rotavirus and pneumococcal diseases (results not shown), no real differences were seen between the 2 groups. These results can be found in the clinical results summary.

Figure 3 Percentages of babies who had protective antibody levels against Hib, rotavirus, pneumococcal bacteria, and hepatitis A



What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record all these events. A summary of all events reported in this study may be found in the clinical results summary.

If the study doctor thinks that the event was caused by the vaccine, they record this as a possible side effect (adverse reaction).

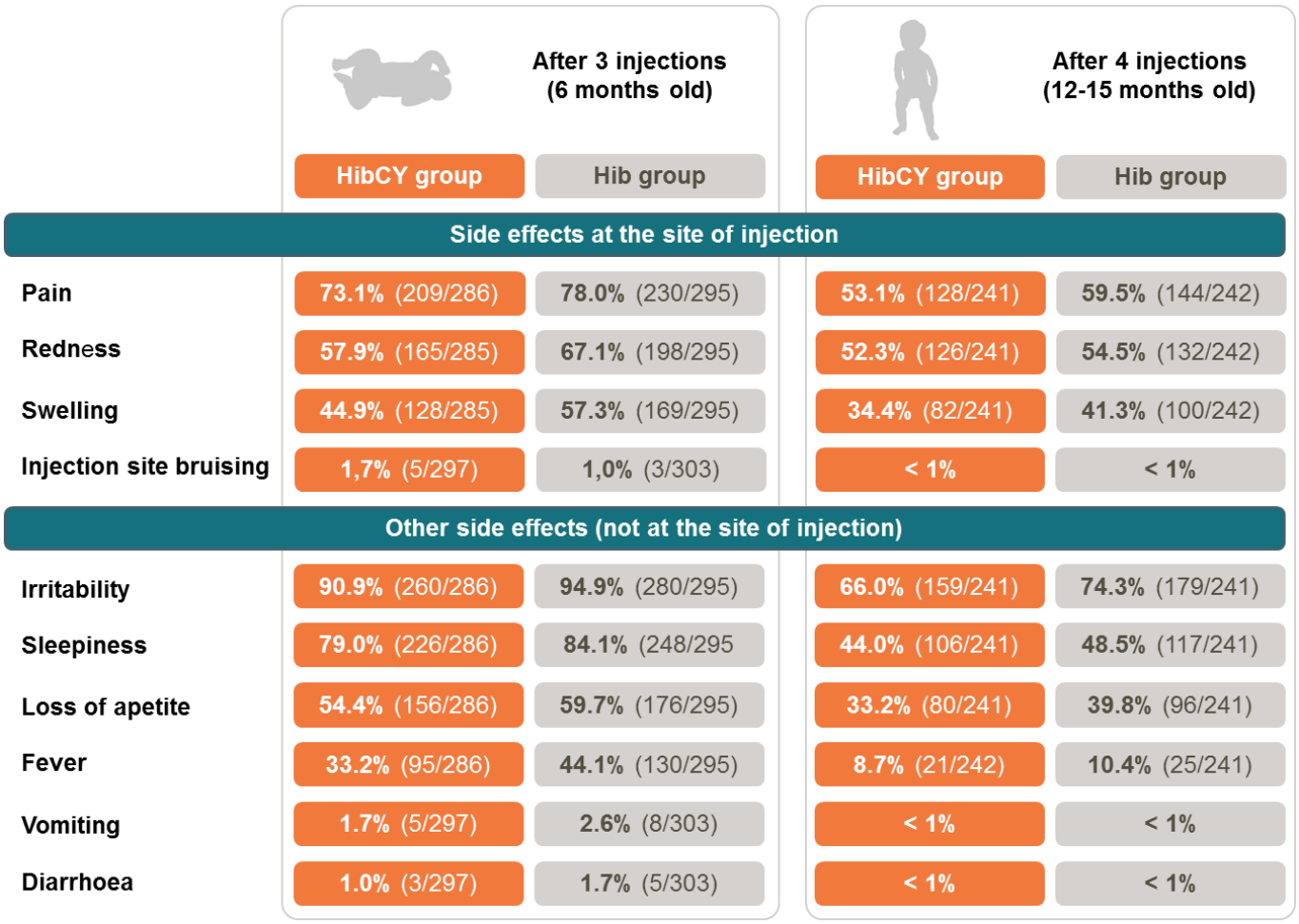
In this summary, "side effects" refer to those events that the study doctor thinks may have been caused by the study vaccine.

The figure below shows the local (at injection site) and other side effects (in the whole body) collected after the respective injections were given.

The most common reported side effect at the site of injection was pain in both groups (**Figure 4**).

The most common general side effect reported for babies was irritability in both groups (**Figure 4**).

Figure 4 Side effects



	After 3 injections (6 months old)		After 4 injections (12-15 months old)	
	HibCY group	Hib group	HibCY group	Hib group
Side effects at the site of injection				
Pain	73.1% (209/286)	78.0% (230/295)	53.1% (128/241)	59.5% (144/242)
Redness	57.9% (165/285)	67.1% (198/295)	52.3% (126/241)	54.5% (132/242)
Swelling	44.9% (128/285)	57.3% (169/295)	34.4% (82/241)	41.3% (100/242)
Injection site bruising	1,7% (5/297)	1,0% (3/303)	< 1%	< 1%
Other side effects (not at the site of injection)				
Irritability	90.9% (260/286)	94.9% (280/295)	66.0% (159/241)	74.3% (179/241)
Sleepiness	79.0% (226/286)	84.1% (248/295	44.0% (106/241)	48.5% (117/241)
Loss of apetite	54.4% (156/286)	59.7% (176/295)	33.2% (80/241)	39.8% (96/241)
Fever	33.2% (95/286)	44.1% (130/295)	8.7% (21/242)	10.4% (25/241)
Vomiting	1.7% (5/297)	2.6% (8/303)	< 1%	< 1%
Diarrhoea	1.0% (3/297)	1.7% (5/303)	< 1%	< 1%

How has this study helped patients and researchers?

The results from this study showed that the HibCY vaccine was similar to the Hib vaccine and can be given to babies together with the other commonly used vaccines.

Are there plans for further studies?

No further studies are planned for the HibCY vaccine.

Where can I find more information about this study?

The detailed title for this research study is:

A phase IIIb, open, randomized, controlled, multicenter study to assess the co-administration of *Rotarix* (GlaxoSmithKline Biologicals') with Hib-MenCY-TT (GlaxoSmithKline Biologicals' Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine) at 2 and 4 months of age, the co-administration of *Prevnar 13* (Pfizer) with Hib-MenCY-TT at 2, 4 and 6 months of age and the co-administration of *Prevnar 13* and *Havrix* (GlaxoSmithKline Biologicals') with Hib-MenCY-TT at 12 to 15 months of age.

Clinical studies have unique study numbers. Below are the unique study numbers associated with this study.

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2013-003459-39
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT01978093

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study.

This document was developed and approved by GSK on <<08-FEB-2019>>. The information in this summary does not include additional information available after this date.

For readers of this document in text form, the websites associated with the hyperlinks above are:

EudraCT summary:
https://www.clinicaltrialsregister.eu/ctr-search/search?query=2013-003459-39

US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT01978093