A phase IV study to evaluate the primary and booster immune responses of UK infants receiving a licensed 6-in-1 DTaP/IPV/Hib/HBV vaccine (Infanrix-Hexa) with a 13valent pneumococcal conjugate vaccine and incorporating a randomisation study of a single dose of 3 different meningococcal group C conjugate vaccines at 3 months of age

Submission date 25/04/2013	Recruitment status  No longer recruiting	<ul><li>[X] Prospectively registered</li><li>Protocol</li></ul>
Registration date 26/04/2013	Overall study status Completed	<ul><li>Statistical analysis plan</li><li>[X] Results</li></ul>
<b>Last Edited</b> 21/06/2019	Condition category Infections and Infestations	[] Individual participant data

## Plain English summary of protocol

Background and study aims

Infants in the UK are routinely immunised against diphtheria, tetanus, pertussis, polio and Haemophilus influenzae serotype b (Hib) using a 5in1 combination vaccine (Pediacel™) given at 2, 3 and 4 months of age. These infants also receive vaccines that protect against meningococcal group C (MenC) and pneumococcal disease as part of this schedule. Hepatitis B is an infection of the liver caused by the Hepatitis B virus (HBV). Chronic (long-term) infection with HBV increases the risk of liver failure, cirrhosis and cancer. The UK currently has a selective HBV immunisation strategy targeting only those considered at high risk of HBV infection. There is an opportunity to introduce a licensed 6in1 vaccine (InfanrixHexa™) to replace the current 5in1 vaccine (Pediacel™) in the infant schedule. This vaccine should protect infants against all the same infections but in addition will protect against hepatitis B. The development of combination vaccines is complex and there is the potential for interactions between the different components of a combination vaccine and also between different vaccines given at the same visit. The aim of this study is to ensure that giving InfanrixHexa™ with MenC and the pneumococcal vaccine as part of UK infant schedule will offer adequate protection against the infections it is designed to protect. In addition, although infants in the UK currently receive two doses of MenC vaccine at 3 and 4 months of age, recent studies have shown that a single MenC dose in infancy provides adequate protection and, therefore, the UK infant schedule will soon move to a single MenC vaccine dose given at 3 months of age. As a result, we aim to randomly allocate infants to receive one of three licensed MenC vaccines at 3 months of age.

Who can participate?

Infants born at term (at least 37 weeks gestation) and aged less than 10 weeks who have not yet received their primary immunisations.

What does the study involve?

Infants are randomly allocated to receive one of three MenC or MenC-containing vaccines at 3 months of age: NeisVacC™, Menjugate™ or Menitorix™. Hib and MenC antibody levels are measured one month later, before routine booster vaccination at 12 months of age.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Health Protection Agency (UK)

When is the study starting and how long is it expected to run for? June 2013 to December 2016

Who is funding the study? Department of Health (UK)

Who is the main contact? Dr Jo Southern jo.southern@phe.gov.uk

# Contact information

### Type(s)

Scientific

#### Contact name

Dr Jo Southern

#### Contact details

Centre for Infections Health Protection Agency 61 Colindale Avenue London United Kingdom NW9 5EQ

jo.southern@phe.gov.uk

# Additional identifiers

Clinical Trials Information System (CTIS)

2012-003026-25

ClinicalTrials.gov (NCT)

NCT01896596

13974

# Study information

#### Scientific Title

A phase IV study to evaluate the primary and booster immune responses of UK infants receiving a licensed 6-in-1 DTaP/IPV/Hib/HBV vaccine (Infanrix-Hexa) with a 13valent pneumococcal conjugate vaccine and incorporating a randomisation study of a single dose of 3 different meningococcal group C conjugate vaccines at 3 months of age

### Acronym

Infanrix-Hexa

### **Study objectives**

Infants in the UK are routinely immunised against diphtheria, tetanus, pertussis, polio and Haemophilus influenzae serotype b (Hib) using a 5in1 combination vaccine (Pediacel™) given at 2, 3 and 4 months of age. These infants also receive vaccines that protect against meningococcal group C (MenC) and pneumococcal disease as part of this primary schedule.

Hepatitis B is an infection of the liver caused by the Hepatitis B virus (HBV). Chronic infection with HBV causes significant morbidity and mortality as there is an increased long term risk of liver failure, cirrhosis and cancer. The UK currently has a selective HBV immunisation strategy targeting only those considered at high risk of HBV infection.

There is an opportunity to introduce a licensed 6in1 vaccine (InfanrixHexa™) to replace the current 5in1 vaccine (Pediacel™) in the infant schedule. This vaccine should protect infants against all the same infections but in addition will protect against hepatitis B.

The development of combination vaccines is complex and there is the potential for interactions between the different components of a combination vaccine and also between different vaccines given at the same visit. The proposed study aims to ensure that giving InfanrixHexa™ with MenC and the pneumococcal vaccine as part of UK infant schedule will offer adequate protection against the infections it is designed to protect. In addition, although infants in the UK currently receive 2 doses of MenC vaccine at 3 and 4 months of age, recent studies have shown that a single MenC dose in infancy provides adequate protection and, therefore, the UK infant schedule will soon move to a single MenC vaccine dose given at 3 months of age. As a result, we aim to randomise infants to receive one of 3 licensed MenC vaccines at 3 months of age.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

First MREC approval date 28/09/2012, ref: 12/LO/1132

## Study design

Randomised interventional study; Design type: Prevention

# Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Immune response to vaccines

#### **Interventions**

Babies taking part in this study will be randomly allocated to receive one of 3 MenC or MenC containing vaccines at 3 months of age: NeisVac<sup>™</sup>, Menjugate<sup>™</sup> or Menitorix<sup>™</sup>. Recent clinical trials have shown that one dose of NeisVac<sup>™</sup> or Menjugate<sup>™</sup> given to babies at 3 months of age provides similar protection against MenC disease as two doses.

### Intervention Type

Biological/Vaccine

#### Phase

Phase IV

### Primary outcome(s)

Hib antibody concentrations and MenC-specific antibody titres measured one month after primary immunisation, prior to routine booster vaccination at 12 months of age

### Key secondary outcome(s))

Not provided at time of registration

### Completion date

31/12/2016

# **Eligibility**

### Key inclusion criteria

- 1. Male or female infants born at term (at least 37 weeks gestation) who are aged <10 weeks and have not yet received their primary immunisations
- 2. With written informed consent obtained from the parent or legal guardian of the infant to participate in the study
- 3. Do not fulfil any of the exclusion criteria

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Neonate

#### Sex

All

#### Total final enrolment

### Key exclusion criteria

- 1. History of infection with Haemophilus influenzae serotype b (Hib), pneumococcal or meningococcal disease, pertussis, polio, diphtheria, tetanus or hepatitis B
- 2. History of maternal acute or chronic hepatitis B infection
- 3. Confirmed or suspected immunosuppressive or immunodeficient condition (including HIV)
- 4. Bleeding disorders and/or prolonged bleeding time
- 5. Major congenital defects or chronic disease
- 6. Premature birth (<37 weeks gestation at birth).
- 7. Previously received any vaccine (particularly hepatitis B)
- 8. Unable to obtain sufficient blood sample during >2 of the 4 blood sampling visits

Temporary Exclusion Criterion - Vaccination will be postponed until resolution of fever if axillary /aural temperature is >= 38°C.

#### Date of first enrolment

01/06/2013

#### Date of final enrolment

31/12/2016

# Locations

#### Countries of recruitment

**United Kingdom** 

England

### Study participating centre Health Protection Agency

London United Kingdom NW9 5EQ

# Sponsor information

### Organisation

Health Protection Agency (UK)

#### **ROR**

https://ror.org/03sbpja79

# Funder(s)

# Funder type

Government

### Funder Name

Department of Health (UK) - Policy Research Programme

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes