# Haemophilus influenzae type b (Hib) immunogenicity study

Submission date 22/10/2008	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 05/01/2009	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 05/01/2009	<b>Condition category</b> Infections and Infestations	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Andrew Pollard

### Contact details

University of Oxford Rm 02-46-07 Childrens Hospital John Radcliffe Hospital Oxford United Kingdom OX3 9DU +44 (0)1865 234226 andrew.pollard@paediatrics.ox.ac.uk

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 2008/03

# Study information

#### Scientific Title

An unblinded phase IV immunogenicity study of the Haemophilus influenzae type b (Hib) conjugate vaccine (Act-Hib®) given as part of the routine infant schedule to children in Kathmandu, Nepal

#### **Study objectives**

1. The Haemophilus influenzae type b (Hib) conjugate vaccine will be immunogenic in the short term, in Nepali infants administered the vaccine as part of the primary immunisation schedule 2. The anti-polyribosylribitol phosphate (anti-PRP) antibody level concentration at 12 months of age, in children administered the Hib conjugate vaccine as a primary 6-, 10- and 14-week immunisation schedule, will be significantly greater than in a group of children who have not previously received Hib vaccine

3. The serum anti-PRP antibody will decrease rapidly after primary vaccination if a booster dose in the second year is not administered

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

1. Nepal Health Research Council gave approval on the 6th August 2008 (ref: 98)

2. Oxford Tropical Research Ethics Committee gave approval on the 7th May 2008 (ref: 16/08)

#### Study design

Multicentre, interventional, unblinded phase IV study

#### Primary study design

Interventional

**Secondary study design** Non randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Haemophilus influenzae type B

#### Interventions

There will be two groups of participants:

Group 1: Participants will receive three doses (0.5 ml intramuscular [IM]) of the Hib conjugate vaccine Act-Hib® at 6, 10 and 14 weeks. A booster dose of the vaccine will be given at 12 months. Three doses of DTP-HepB (0.5 ml IM) will be given (routine schedule) and three doses of oral polio (2 drops orally, routine schedule) will also be given. A blood sample will be taken at 18 weeks, 52 weeks and 56 weeks.

Group 2: Participants will receive one dose (0.5 ml IM) of the Hib conjugate vaccine Act-Hib® at 12 months. A blood sample will be taken at 52 weeks and 56 weeks.

Both groups will receive one dose (0.5 ml IM) of the Varicella vaccine, GCC (Green Cross Corp), at 56 weeks.

#### Intervention Type

Drug

### Phase

Phase IV

### Drug/device/biological/vaccine name(s)

Hib conjugate vaccine (Act-Hib®), Diphtheria Tetanus Pertussis-Hepatitis B (DTP-HepB) vaccine, oral polio vaccine, Varicella vaccine

#### Primary outcome measure

The geometric mean anti-PRP concentration at 52 weeks of age following a primary schedule of immunisation with the Hib vaccine (Act-Hib®) given to healthy infants in Kathmandu.

#### Secondary outcome measures

 The geometric mean anti-PRP concentration at 18 weeks of age following a primary schedule of immunisation with the Hib vaccine (Act-Hib®) given to healthy infants in Kathmandu
 The demonstration of a significant difference or not in geometric mean anti-PRP antibody concentration at 52 weeks of age in infants immunised with Hib (Act-Hib®) versus those receiving non-Hib containing primary immunisation

3. The geometric mean anti-PRP antibody concentration at 56 weeks of age following booster immunisation with the Hib vaccine, after a primary schedule of immunisation with the Hib vaccine 4. The demonstration of a significant difference or not in the proportion of individuals with anti-PRP concentrations above the accepted measures of short and long-term protection in infants immunised with Hib (Act-Hib®) versus those receiving non-Hib containing primary immunisation

### Overall study start date

21/08/2008

Completion date 21/08/2009

# Eligibility

### Key inclusion criteria

Group 1:

1. Parent/carer of participant is willing and able to give informed consent for participation in the study

- 2. In good health as determined by:
- 2.1. Medical history
- 2.2. Physical examination
- 2.3. Clinical judgement of the investigator
- 3. Male or female, aged 40 60 days
- 4. Participants residing in Kathmandu

5. Parents able (in the investigators opinion) and willing to comply with all study requirements

#### Group 2:

1. Parent/carer of participant is willing and able to give informed consent for participation in the study

- 2. In good health as determined by:
- 2.1. Medical history
- 2.2. Physical examination
- 2.3. Clinical judgement of the investigator
- 3. Male or female, aged 48 56 weeks
- 4. Participants residing in Kathmandu
- 5. Parents able (in the investigators opinion) and willing to comply with all study requirements

### Participant type(s)

Patient

#### Age group

Neonate

Sex

Both

#### Target number of participants

A total of 165 infants; Group 1 = 90 infants, Group 2 = 75 infants

#### Key exclusion criteria

Group 1:

- 1. Parent/carer unwilling or unable to give written informed consent to participate in the study
- 2. Previous immunisation (excluding Bacillus Calmette-Guerin [BCG] and hepatitis B)
- 3. Premature birth (less than 37 weeks gestation)
- 4. Previous hospital admission

5. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

Group 2:

1. Parent/carer unwilling or unable to give written informed consent to participate in the study

- 2. Previous immunisation with Hib vaccine
- 3. Premature birth (less than 37 weeks gestation)
- 4. Previous hospital admission in the last one month

5. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

#### Date of first enrolment

21/08/2008

Date of final enrolment 21/08/2009

### Locations

**Countries of recruitment** England

Nepal

United Kingdom

**Study participating centre University of Oxford** Oxford United Kingdom OX3 9DU

## Sponsor information

**Organisation** University of Oxford (UK)

Sponsor details c/o Heather House Clinical Trials & Research Governance Manor House John Radcliffe Hospital Headington Oxford England United Kingdom OX3 9DU +44 (0)1865 222757 heather.house@admin.ox.ac.uk

**Sponsor type** University/education

Website http://www.ox.ac.uk/

#### ROR

# Funder(s)

**Funder type** University/education

**Funder Name** University of Oxford (UK) - Department of Paediatrics

# **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration