# Haemophilus influenzae type b (Hib) immunogenicity study

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

**Prof Andrew Pollard** 

#### Contact details

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# Additional identifiers

Protocol serial number 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

#### Study type(s)

Treatment

# 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(s)

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.

#### Key secondary outcome(s))

- 1. 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
- 2. 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Neonate

#### Sex

All

#### 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

United Kingdom

**England** 

Nepal

## Study participating centre

#### **University of Oxford** Oxford

United Kingdom OX3 9DU

# Sponsor information

## Organisation

University of Oxford (UK)

#### **ROR**

https://ror.org/052gg0110

# Funder(s)

#### Funder type

University/education

#### **Funder Name**

University of Oxford (UK) - Department of Paediatrics

# **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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes