ISRCTN58764892 https://doi.org/10.1186/ISRCTN58764892

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
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
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

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

https://ror.org/052gg0110

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