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Assessment of serological responses to Hepatitis B and Hib vaccines in infants receiving vitamin A (Ghana)

Submission date	Recruitment status	[_] Prospectively registered
04/08/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2022	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/RPC041

Study information

Scientific Title
Assessment of serological responses to Hepatitis B and Hib vaccines in infants receiving vitamin A (Ghana)

Study objectives
Hypothesis:
The simultaneous administration of vitamin A with the pentavalent vaccine may reduce or enhance the serological response to Hepatitis B and Haemophilus influenzae type b vaccines in infants.

Aim:
To evaluate the seroconversion rates of administering the pentavalent vaccine with vitamin A supplements using two different supplementation regimes. That is:
1. Supplementation of mothers with 400,000 IU vitamin A at 6 weeks in two divided doses and supplementation of children with 50,000 IU vitamin A at 6,10 and 14 weeks
2. Supplementation of mothers alone with 400,000 IU vitamin A at 6 weeks in two divided doses

Specific objectives:
1. To measure the antibody response to Hepatitis B vaccination and Haemophilus influenza type b vaccination in infants given 50,000 IU of vitamin A at 6,10 and 14 weeks and whose mothers were given 400,000 IU of vitamin A at 6 weeks post partum
2. To measure the antibody response to Hepatitis B vaccination and Haemophilus influenza type b vaccination in infants whose mothers only were given 400,000 IU of vitamin A at 6 weeks post partum
3. To assess the impact of vitamin A given to infants at the time of vaccination (6, 10, and 14 weeks) on the seroconversion rates of Hepatitis B and Haemophilus influenza b vaccines

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the World Health Organization (WHO) Secretariat Committee on Research Involving Human Subjects (SCRIHS) - conditional approval received on 12th December 2003, amendments approved on 6th April 2007.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Immunology/vaccines

Interventions
Treatment group:
1. Mothers at 6 weeks: 200,000 IU Vitamin A x 2 (day 1 and day 2)
2. Infants at 6, 10 and 14 weeks: 50,000 IU Vitamin A and Diphtheria, Pertussis, Tetanus (DPT), Hepatitis B (HepB) and Haemophilus influenzae type b (Hib) vaccines

Control group:
1. Mothers 200,000 IU Vitamin A x 2 (day 1 and day 2)
2. Infants: DPT, HepB and Hib alone

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin A supplementation

Primary outcome measure
The impact of the different doses of vitamin A on the pentavalent vaccines will be assessed by comparing the two groups in terms of their seroconversion rates for:
1. Hepatitis B
2. Haemophilus influenzae type b

The choice of four months for reevaluation is because this is the age at which it is presently recommended to determine the seroconversion rates. Accordingly, pre-samples will be taken at 6 weeks prior to DPT-HepB Hib immunisation and post samples will be taken at 1 month after the DPT-HepB Hib immunisation.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2004

Completion date
31/12/2006

Eligibility

Key inclusion criteria

1. Live-born infants
2. Willingness of mothers to participate in the study
3. Must reside in the study area for at least 4 months after the birth
4. Consent to two blood samples before and after their child's vaccination

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
1042 mother-infant pairs.

Total final enrolment
1077

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Ghana

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

Sponsor details
20, Avenue Appia
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Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2007		Yes	No