

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

Submission date
04/08/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/09/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/11/2022

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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