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Prevention of vitamin A deficiency by supplementation alongside routine vaccinations: a randomised controlled trial in Ghana infants

Submission date 24/11/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/11/2004	**Overall study status** Completed	
Last Edited 26/10/2007	**Condition category** Nutritional, Metabolic, Endocrine	

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

N/A

Study information

Scientific Title

Study objectives
The primary objectives of the proposed trial are to:
1. Measure the effect of 400,000 IU of vitamin A given in two divided doses of 200,000 IU to mothers, and 3 doses of 50,000 IU of vitamin A given to their infants concurrently with Diphtheria, Pertussis and Tetanus (DPT)/Polio immunisations, on vitamin A status of the infants at 26 weeks of age
2. Compare the effect of such a regimen to that of the previously recommended regimen of 200,000 IU of vitamin A given to mothers and 3 doses of 25,000 IU of vitamin A given to their infants concurrently with DPT/Polio immunisations
3. Measure the side effects of 50,000 IU of vitamin A administered with DPT/Polio immunisations

The outcomes to be monitored for the above objectives include serum retinol levels, modified Retinol Dose Response (mRDR) tests, incidence of side effects such as bulging of the anterior fontanel and vomiting, and incidence of severe morbidity.

The secondary objectives are to:
4. Measure the effect of the maternal dose on breast milk retinol levels up to 9 months post partum
5. Examine if any impacts on infant vitamin A status are sustained beyond 6 months of age up to 9 months of age

Outcomes to be monitored for the secondary objectives include breast milk retinol concentrations and mRDR testing of infants at 9 months of age.

Related to the main objectives, the following hypotheses will be tested:
1. Giving 400,000 IU of vitamin A to mothers within 6 weeks of delivery, plus 50,000 IU given to their infants with their DPT/Polio immunisations, will improve infants' vitamin A status as measured by mean serum retinol, or by proportions below 20 ug/dl, or proportions of abnormal mRDR at 6 months of age. The proportion of infants with serum retinol concentration below 20 ug/dl will be reduced by 66% from 43%, which was achieved by the 25,000 IU-dosing regimen. Similarly, the proportion of infants with mRDR ratio greater than or equal to 0.06 will be reduced by 66% from 44%, which was achieved by 25,000 IU-dosing regimen.
2. Giving 50,000 IU of vitamin to infants with their DPT/Polio immunisations will produce no clinically significant side effects

The following additional hypotheses will be tested for the secondary objectives:
3. Giving 400,000 IU of vitamin to mothers in the post partum period will result in a greater improvement in breast milk retinol levels than that achieved with 200,000 IU, and that this improvement will be sustained up to 9 months
4. The improvement to infant vitamin A status at 6 months of age, due to the newly proposed supplementation regime, will be sustained beyond 6 months up to 9 months of age

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Ethical Review Committee of the Ministry of Health (Ghana) on the 24th September 2001
2. London School of Hygiene and Tropical Medicine Ethics Committee on the 29th April 2002

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
Vitamin A Deficiency

Interventions
1st Group:
1. Mothers 200,000 IU Vitamin A shortly after delivery
2. Infants: 25,000 IU Vitamin A with each Diphtheria, Pertussis, Tetanus (DPT) vaccine 1, 2 and 3

2nd Group:
1. Mothers 200,000 IU Vitamin A at infant's Bacillus Calmette-Guerin (BCG) vaccine and another 200,000 IU Vitamin A at infant's 1st DPT
2. Infants: 50,000 IU Vitamin A with each DPT 1, 2 and 3

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure
1. Serum retinol levels, assessed by carrying out mRDR testing of infants at 6 weeks, 6 months and 9 months
2. Modified Retinol Dose Response (mRDR) tests
3. Incidence of side effects such as bulging of the anterior fontanel and vomiting
4. Incidence of severe morbidity

Secondary outcome measures
1. Breast milk retinol concentrations, assessed at 6 weeks, 6 months and 9 months for an assessment of the impact of the different supplementation regimes
2. mRDR testing of infants at 9 months of age

Overall study start date
01/01/2004

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Mothers normally resident in the study area
2. Informed consent obtained from the mother

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
1,400 mother-infant pairs.

Key exclusion criteria
1. Mothers unable to give informed consent
2. Mothers considered to be at high risk of adverse outcome in puerperal period
3. Multiple deliveries
4. Severe adverse reaction to vitamin A supplementation

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2006

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)

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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

IPD sharing plan summary
Not provided at time of registration