ISRCTN98554309 https://doi.org/10.1186/ISRCTN98554309

Optimisation of vitamin A dosing schedules in infancy

Submission date	Recruitment status
30/08/2005	No longer recruiting
Registration date	**Overall study status**
10/10/2005	Completed
Last Edited	**Condition category**
27/07/2007	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Early high-dose vitamin A supplementation of mothers and infants improves vitamin A status and protects against mucosal infections, growth faltering and illness compared to the standard World Health Organisation (WHO) regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

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
Early high dose Vitamin A schedule versus standard WHO schedule.

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure

1. Vitamin A status in mothers and infants
2. Heliobacter pylori infection in infants
3. Nasopharyngeal pneumococcal carriage in mothers and infants
4. Gut permeability in infants assessed by Dual Pugar Permeability Test (DSPT)

Secondary outcome measures
1. Infant growth
2. Infant morbidity
3. Breast milk sodium-potassium ratios
4. Breast-milk oligosaccharides

Overall study start date
01/09/2001

Completion date
01/10/2004

Eligibility

Key inclusion criteria
Consenting mothers and new born infants in six villages in the West Kiang region of The Gambia.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Congenital defects
2. Birthweight under 2200 g

Date of first enrolment
01/09/2001

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
England

Gambia

United Kingdom

Study participating centre
MRC International Nutrition Group
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	23/06/2007		Yes	No