

Optimisation of vitamin A dosing schedules in infancy

Submission date 30/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/07/2007	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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. Helicobacter 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
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Sponsor information

Organisation
Medical Research Council (UK)

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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