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Long-chain n-3 polyunsaturated fatty acids in relation to gut integrity, growth failure and cognitive development of rural African infants

Submission date
14/03/2007

Recruitment status
No longer recruiting

Registration date
31/05/2007

Overall study status
Completed

Last Edited
12/12/2012

Condition category
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

SCC1061

Study information

Scientific Title

Acronym
IN3SS (Infant N-3 Supplementation Study)

Study objectives
Current hypotheses as of 12/01/2009:

Primary hypotheses:
1. Dietary n-3 long-chain polyunsaturated fatty acid (LCP) supplementation will improve rural African infants' growth performances
2. Dietary n-3 LCP supplementation will protect infant mucosal epithelial integrity

Secondary hypotheses:
1. Dietary n-3 LCP supplementation improves infant plasma n-3 fatty acid status
2. Dietary n-3 LCP supplementation will enhance the cognitive development of rural African infants
3. Dietary n-3 LCP supplementation will reduce the degree of intestinal inflammation of rural African infants
4. Dietary n-3 LCP supplementation will reduce infant systemic inflammation
5. Dietary n-3 LCP supplementation reduces incidence and severity of morbidities in rural African infants

Previous hypotheses:

Primary hypothesis:
Dietary long-chain n-3 polyunsaturated fatty acids (PUFA) supplementation may improve infant growth performance and head circumference (HC) measurements.

Secondary hypothesis:
Dietary long-chain n-3 PUFA supplementation may protect infant mucosal epithelial integrity and reduce mucosal inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine Ethics Board, approved on 9 January 2007. Ref: 5072
2. Joint Medical Research Council Scientific Coordinating Committee/Gambian Government Ethics Committees, approved on 29 March 2007. Ref: SCC 1061

Study design
Randomised double-blind placebo-controlled parallel-group trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Infant growth and gut integrity

Interventions
Current interventions as of 12/01/2009:
The active group will receive 2 ml per day of highly purified fish oil (200 mg docosahexaenoic acid [DHA] and 300 mg eicosapentaenoic acid [EPA]) supplied by Nordic Naturals Inc, USA, for six months. The dosage was designed to achieve a substantial increase in plasma n-3 PUFA to both eliminate any existing deficiencies and to elicit a therapeutic response.

Previous interventions:
The active group will receive 2 ml per day of highly purified fish oil (500 mg docosahexaenoic acid [DHA] and 500 mg eicosapentaenoic acid [EPA]) supplied by Nordic Naturals Inc, USA, for six months. The dosage was designed to achieve a substantial increase in plasma n-3 PUFA to both eliminate any existing deficiencies and to elicit a therapeutic response.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
n-3 PolyUnsaturated Fatty Acids

Primary outcome measure
The following will be assessed at 3 and 9 months of age (i.e. at baseline and 6-month follow-up):

1. Infant anthropometric indicators
2. Gut permeability (dual sugar permeability test)

Secondary outcome measures
Current secondary outcome measures as of 12/01/2009:
1. Plasma fatty acid status (gas chromatography [GC])
2. Infant cognitive development (infant planning test and attention assessment)
3. Systemic inflammatory markers (a-acid glycoprotein [AGP], C-reactive protein [CRP] and

plasma albumin)
4. Intestinal inflammation (faecal calprotectin)
5. Infant morbidities (daily morbidity assessments, clinic/nurse visits)

Measures 1, 3 and 4 will be measured at 3 and 9 months of age (i.e. at baseline and 6-month follow-up). Measure 2 will be measured at 12 months of age.

Previous secondary outcome measures:
The following secondary outcomes will also be measured at 3 and 9 months of age (i.e. at baseline and 6-month follow-up):
1. Plasma fatty acid status (gas chromatography [GC]) and systemic inflammatory markers (α-acid glycoprotein [AGP], C-reactive protein [CRP] and plasma albumin)
2. Intestinal inflammation (faecal neopterin and calprotectin)

Tertiary outcome measure: Daily morbidity assessments

Overall study start date
02/04/2007

Completion date
04/04/2008

Eligibility

Key inclusion criteria
1. Infants born in the larger villages of the West Kiang region of The Gambia
2. Aged 3 months
3. Not currently enrolled in any other study

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Severe congenital abnormalities that could affect growth and development
2. Known HIV infection

Added as of 12/01/2009:
3. Infants from multiple births

Date of first enrolment
02/04/2007

Date of final enrolment
04/04/2008

Locations

Countries of recruitment
England

Gambia

United Kingdom

Study participating centre
Medical Research Council International Nutrition Group
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Sponsor information

Organisation
Medical Research Council (UK)

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Sponsor type
Government

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ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

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

Funder Name
Overseas Research Students Awards Scheme (ORSAS) (UK)

Funder Name
Ernest Oppenheimer Memorial Trust (South Africa)

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	01/01/2013		Yes	No