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Investigating the effects of pre-natal and infancy nutritional supplementation on infant immune development in The Gambia: the Early Nutrition and Immune Development (ENID) trial

Submission date 24/08/2009	**Recruitment status** No longer recruiting	✓ Retrospectively registered ✓ Protocol added ? SAP not yet added ✓ Results added ? Raw data not yet added ✓ Study completed
Registration date 12/11/2009	**Overall study status** Completed	
Last Edited 31/03/2021	**Condition category** Pregnancy and Childbirth	

Plain English Summary
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

Protocol/serial number
SCC 1126v2

Study information

Scientific Title
A randomised trial to investigate the effects of pre-natal and infancy nutritional supplementation on infant immune development

Acronym
ENID

Study hypothesis
Early life immunocompetence can be enhanced by a 'life-course' approach to achieve nutritional repletion in late gestation and infancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Gambia Government/MRC The Gambia Joint Ethics Committee, 20/08/2008, ref: SCC 1126v2

Study design
Three-way randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Optimisation of nutritional status for immune development

Interventions
Four pregnancy interventions, to be given daily from 12 weeks gestation until delivery:
1. FeFol: Iron-folate, 60 mg iron 400 µg folate, representing the usual standard of care during pregnancy, as per Gambian Government guidelines (control group).

2. MMN: Multiple micronutrients. A combination of 15 micronutrients, specifically designed for use during pregnancy, and as formulated by UNICEF. A single tablet provides the Recommended Dietary Allowance (RDA) for each micronutrient, but we will supplement women in this arm of the trial with two daily MMN tablets.
3. PE + FeFol: Protein-energy and iron-folate. A food-based supplement developed by Valid International, providing a comparable level of iron and folate to the FeFol only arm, but with the addition of energy, protein and lipids.
4. PE + MMN: Protein-energy and multiple micronutrients. A micronutrient fortified food-based supplement also developed by Valid International, and providing comparable levels of micronutrients to the MMN arm (including FeFol), in addition to the energy and protein and lipid content.

From 6 months of age, infants will further be randomised to receive a nutrient enriched weaning food fortificant or placebo, and for a period of 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Thymic index at 1, 8, 24 and 52 weeks of age
2. Antibody response to EPI vaccines (diphtheria, tetanus toxoid, HiB, measles)

Secondary outcome measures
Cellular markers of immunity in a randomly selected sub-cohort of infants, stratified by treatment group. The secondary outcome measurements will be assessed when the infants are 12, 24 and 52 weeks of age.

Overall study start date
01/10/2009

Overall study end date
30/09/2013

Eligibility

Participant inclusion criteria
Amended as of 04/10/2010:
Women (aged 18 to 45 years) resident in Kiang West Region, The Gambia, with pregnancy confirmed by urine test and ultrasound examination and with gestational age approximately 10 - 20 weeks.

Initial information at time of registration:
Women (aged 18 to 45 years) resident in Kiang West Region, The Gambia, with pregnancy confirmed by urine test and ultrasound examination and with gestational age approximately 12 weeks

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
800 mother-infant pairs

Total final enrolment
875

Participant exclusion criteria
Amended as of 04/10/2010:
1. Currently enrolled in another MRC study or current pregnancy (beyond 20 weeks on ultrasound assessment)
2. Severe anaemia (haemoglobin [Hb] less than 7 g/dL)
3. Reported onset of menopause

Initial information at time of registration:
1. Currently enrolled in another MRC study or current pregnancy (beyond 12 weeks on ultrasound assessment)
2. Severe anaemia (haemoglobin [Hb] less than 7 g/dL)
3. Reported onset of menopause

Recruitment start date
01/10/2009

Recruitment end date
30/09/2013

Locations

Countries of recruitment
Gambia

Study participating centre
MRC Keneba
Banjul
Gambia
PO Box 273

Sponsor information

Organisation
Medical Research Council (MRC) (UK) - International Nutrition Group

Sponsor details
MRC London Centre
Stephenson House
158 - 160 North Gower Street
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United Kingdom
NW1 2ND
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Sponsor type
Research council

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

ROR
https://ror.org/050pqs331

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council - International Nutrition Group Core Funding

Alternative Name(s)
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?
Protocol article	protocol	11/10/2012		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/06/2017		Yes	No
Results article	results	01/06/2017		Yes	No
Results article	results	18/02/2019		Yes	No
Results article	results	06/08/2019	10/01/2020	Yes	No
Results article		01/07/2021	31/03/2021	Yes	No