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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

Registration date
12/11/2009

Overall study status
Completed

Last Edited
31/03/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] 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

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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
1. Thymic index at 1, 8, 24 and 52 weeks of age
2. Antibody response to EPI vaccines (diphtheria, tetanus toxoid, HiB, measles)

Key secondary outcome(s))
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.

Completion date
30/09/2013

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
875

Key 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

Date of first enrolment
01/10/2009

Date of final enrolment
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

ROR
https://ror.org/050pqs331

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council - International Nutrition Group Core Funding

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

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	01/01/2014		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
Protocol article	protocol	11/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes