

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	☐ Prospectively registered ☒ Protocol
Registration date 12/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/03/2021	Condition category Pregnancy and Childbirth	☐ 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

Primary study design

Interventional

Study design

Three-way randomised controlled trial

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, Medical Research Committee and Advisory 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