

# 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

<b>Submission date</b> 24/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/03/2021	<b>Condition category</b> Pregnancy and Childbirth	<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

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

## 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

## 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 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

### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

800 mother-infant pairs

**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

**Sponsor details**

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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)**

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?
<a href="#">Protocol article</a>	protocol	11/10/2012		Yes	No
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Results article</a>	results	01/06/2017		Yes	No
<a href="#">Results article</a>	results	01/06/2017		Yes	No
<a href="#">Results article</a>	results	18/02/2019		Yes	No
<a href="#">Results article</a>	results	06/08/2019	10/01/2020	Yes	No
<a href="#">Results article</a>		01/07/2021	31/03/2021	Yes	No