

# 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
<b>Registration date</b> 12/11/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 31/03/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sophie Moore

**Contact details**  
MRC Keneba  
MRC Laboratories  
Fajara  
Banjul  
Gambia  
PO Box 273  
-  
smoore@mrc.gm

## 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, 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?
<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
<a href="#">Protocol article</a>	protocol	11/10/2012		Yes	No