

# Periconceptual multi-micronutrient supplementation and placental function in rural Gambian women

<b>Submission date</b> 21/07/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/11/2015	<b>Condition category</b> Neonatal Diseases	<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 1000

# Study information

## Scientific Title

Periconceptual multi-micronutrient supplementation and placental function in rural Gambian women: a randomised controlled trial

## Acronym

PMMST

## Study objectives

Improved maternal micronutrient status prior to conception and during early pregnancy results in improved placental growth and functional parameters, relevant to fetal growth and physiological development.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Research Council (MRC) and the Gambian Government Ethics Committee, 13/03/2006, reference numbers: SCC1000 and L2005.111, respectively

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Fetal growth restriction

## Interventions

UNICEF Maternal multi-micronutrient supplement (UNIMMAP)  
Placebo

## Intervention Type

Supplement

**Primary outcome measure**

1. The ratio of plasminogen activator inhibitor-1 (PAI-1) to plasminogen activator inhibitor-2 (PAI-2) at 20 weeks gestation
2. Placental doppler flows at 20 weeks
3. Placental transfer of pathogen specific IgG at delivery

Primary outcomes amended from the following on 20/03/2006:

1. Placental volume at 20 weeks gestation
2. Placental doppler flows at 20 weeks
3. Placental transfer of pathogen specific IgG at delivery

**Secondary outcome measures**

1. Maternal serum human chorionic gonadotropin (hCG) and human placental lactogenic (hPL) concentration at 20 weeks
2. The ratio of PAI-1 to PAI-2 at 30 weeks, and at delivery
3. Placental doppler waveforms at 30 weeks
4. Change in maternal haematological status from baseline to 20 and 30 weeks gestation, and at delivery
5. Change in maternal micronutrient status from baseline to 20 and 30 weeks gestation, and at delivery
6. Fetal anthropometry at 20, 30 weeks and at delivery
7. Placental weight at delivery

Secondary outcomes amended from the following as of 20/03/2006:

1. Placental endocrine function (hCG; hPL) at 20 weeks
2. Placental volume at 30 weeks
3. Placental doppler waveforms at 30 weeks
4. Fetal anthropometry at 20, 30 weeks and at delivery
5. Placental weight at delivery
6. Placental transport function (essential amino acids) at delivery

**Overall study start date**

01/09/2005

**Completion date**

30/03/2008

**Eligibility****Key inclusion criteria**

Women of reproductive age (17 years to 45 years) living in West Kiang, The Gambia.

The age inclusion criteria was previously 15 to 45 years of age, amendment date: 20/03/2006

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

3000

**Key exclusion criteria**

1. Women known to be already pregnant
2. Women breastfeeding infants less than 1 year of age
3. Women found to be severely anaemic at recruitment (haemoglobin concentration <7 g/dl)

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

30/03/2008

## **Locations**

**Countries of recruitment**

Gambia

**Study participating centre**

MRC Laboratories

Fajara

Gambia

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## **Sponsor information**

**Organisation**

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

**Sponsor details**

London School of Hygiene and Tropical Medicine

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**Sponsor type**

Research council

**ROR**

<https://ror.org/03x94j517>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council (UK) 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="#">Results article</a>	results	01/12/2015		Yes	No