

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

London

United Kingdom

WC1E 7HT

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andrew.prentice@lshtm.ac.uk

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?
Results article	results	01/12/2015		Yes	No