ISRCTN13687662 https://doi.org/10.1186/ISRCTN13687662

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

Submission date 21/07/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/08/2005	**Overall study status** Completed	
Last Edited 13/11/2015	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Owens

Contact details
MRC Laboratories
P.O. Box 273
Fajara
Gambia
-
+220 9812617
sowens@mrc.gm

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fetal growth restriction

Interventions
UNICEF Maternal multi-micronutrient supplement (UNIMMAP)
Placebo

Intervention Type
Supplement

Primary outcome(s)
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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
-

Sponsor information

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

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, 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	01/12/2015		Yes	No