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Effects on birth weight and perinatal mortality of maternal dietary supplements in rural Gambia

Submission date
05/02/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
26/02/2014

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low birth weight is a major contributor to mortality during infancy. This study was designed to see if supplementing rural African women with a high energy and protein dietary supplement from mid-pregnancy to delivery would improve both low birth weight and infant survival.

Who can participate?
The study enrolled consenting pregnant women living in the West Kiang region of The Gambia.

What does the study involve?
This study is completed, having run between January 1989 and October 1994. Women in 28 villages in rural Gambia were randomly allocated to one of two groups: to receive a biscuit supplement from either mid-pregnancy to delivery (intervention group) or from delivery for 20 weeks (control group). Birth weight, length and head circumference and survival of the infants up to 12 months of age was assessed.

What are the possible benefits and risks of participating?
These are the findings of the study: Supplementation during pregnancy increased birth weight by 136g. The supplement had greatest impact when given during the nutritionally poor 'hungry season (+201g). In addition, the supplement reduced the prevalence of babies born with a low birth weight (<2500g). Supplementation also reduced the risk of stillbirths and deaths during the first week of life. This study showed that giving a high energy and protein supplement to women during pregnancy in rural Gambia can improve birth weight and early neonatal survival.

Where is the study run from?
The study was run from the Medical Research Council (UK) Keneba field station, in Keneba, The Gambia.

When is the study starting and how long is it expected to run for?
The study started in 1989 and field work was completed in 1994. It was published in 1997.

Who is funding the study?
The study was funded by the Medical Research Council (UK), the Overseas Development Administration (UK) and the Nestle Foundation (Switzerland).

Who is the main contact?
Professor Andrew Prentice
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Contact information

Type(s)
Scientific

Contact name
Prof Andrew Prentice

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects on birth weight and perinatal mortality of maternal dietary supplements in rural Gambia: 5 year randomised controlled trial

Study objectives
Antenatal high-energy supplementation improves birth weight and infant survival in rural Gambia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval given by the joint Gambia Government / MRC Unit The Gambia Ethics Committee.

Study design
5 year cluster randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not provided at time of registration - N/A as study ended in 1994.

Health condition(s) or problem(s) studied
Pregnancy and lactation

Interventions
5 year cluster randomized trial of pregnant women in 28 villages in rural Gambia to daily supplementation with high energy biscuits for 20 weeks pre-delivery (intervention) or post-delivery (control).

Two biscuits daily, made locally from roasted groundnuts, rice flour, sugar and groundnut oil and providing a maximum daily intake of 4250 kJ energy, 22 g protein, 56 g fat, 47 mg calcium and 1.8 mg iron. Biscuits were distributed to birth attendants in each village, who issued them to participating women and observed consumption.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Birth weight
2. Neonatal and postneonatal mortality

Secondary outcome measures
1. Prevalence of low birth weight (< 2500g)
2. Head circumference
3. Birth length
4. Gestational age
5. Prevalence of stillbirths

Overall study start date
01/01/1989

Completion date
31/10/1994

Eligibility

Key inclusion criteria
1. Pregnant, with < 20 weeks gestation
2. Resident in West Kiang region of The Gambia

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2047

Key exclusion criteria
Twin pregnancies

Date of first enrolment
01/01/1989

Date of final enrolment
31/10/1994

Locations

Countries of recruitment
England

Gambia

United Kingdom

Study participating centre
MRC International Nutrition Group
London
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Sponsor information

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

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Sponsor type
Research council

Website
http://www.ing.mrc.ac.uk

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council, Overseas Development Administration and Nestle Foundation.

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	27/09/1997		Yes	No
Results article	results	01/01/2014		Yes	No