

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

Submission date 05/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/02/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

1. Birth weight
2. Neonatal and postneonatal mortality

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Twin pregnancies

Date of first enrolment

01/01/1989

Date of final enrolment

31/10/1994

Locations**Countries of recruitment**

United Kingdom

England

Gambia

Study participating centre

MRC International Nutrition Group

London

United Kingdom

WC1E 7HT

Sponsor information**Organisation**

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

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