

# Calcium requirements of pregnant women in The Gambia

<b>Submission date</b> 11/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/11/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/06/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Ann Prentice

**Contact details**  
MRC Human Nutrition Research  
Elsie Widdowson Laboratory  
Fulbourn Road  
Cambridge  
United Kingdom  
CB1 9NL  
-  
ann.prentice@mrc-hnr.cam.ac.uk

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**

Nil known

## Study information

### Scientific Title

Calcium requirements of pregnant women in The Gambia

### Study objectives

Calcium intakes of pregnant women in rural areas of The Gambia are considerably below recommended levels. There is evidence to suggest that low calcium intakes during pregnancy may be associated with an increased incidence of pregnancy-induced hypertension, reduced maternal bone mineral content, low breast-milk calcium concentrations post-partum, and sub-optimal bone development and growth of the child. The aim of this study is to determine whether pregnant Gambian women would benefit from an increase in calcium intake.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Medical Research Council (MRC)/Gambian Government Joint Ethics Committee (ref: SCC/EC 585/559).

### Study design

Randomised double blind placebo controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### 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

Calcium deficiency in pregnancy

### Interventions

1500 mg Calcium (Ca) orally per day or placebo until delivery.

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Calcium

**Primary outcome measure**

1. Maternal blood pressure at 36 - 38 weeks gestation
2. Breast-milk calcium concentration during lactation
3. Post-partum bone mineral content of mother and baby

**Secondary outcome measures**

1. Infant growth and development:
  - 1.1. Weight, measured within 24 hours of birth and at 2, 13 and 52 weeks
  - 1.2. Crown-heel length, measured within 5 days from birth and at 2, 13 and 52 weeks
  - 1.3. Head circumference measured within 5 days from birth and at 2, 13 and 52 weeks
2. Infant blood pressure and growth, measured every two years from age 3
3. Maternal post-partum blood pressure, measured at 2, 13 and 52 weeks post-partum

**Overall study start date**

01/01/1995

**Completion date**

31/12/2000

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

Consenting pregnant women at booking.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

600

**Key exclusion criteria**

No specific exclusion criteria at booking.

**Date of first enrolment**

01/01/1995

**Date of final enrolment**

31/12/2000

# Locations

## Countries of recruitment

England

Gambia

United Kingdom

## Study participating centre

**MRC Human Nutrition Research**

Cambridge

United Kingdom

CB1 9NL

# Sponsor information

## Organisation

Medical Research Council (UK)

## Sponsor details

20 Park Crescent

London

United Kingdom

WC1E 7HT

-

corporate@headoffice.mrc.ac.uk

## Sponsor type

Government

## Website

<http://www.mrc.ac.uk>

## ROR

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

# Funder(s)

## Funder type

Government

**Funder Name**  
Medical Research Council (MRC) (UK)

**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	01/03/2006		Yes	No
<a href="#">Results article</a>	results	01/08/2010		Yes	No
<a href="#">Results article</a>	results	01/12/2011		Yes	No
<a href="#">Results article</a>	follow-up study results	01/09/2013		Yes	No
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Results article</a>	follow-up on blood pressure and growth	18/04/2024	11/06/2024	Yes	No