

# 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

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## Study type(s)

Prevention

## 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(s)

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

## Key secondary outcome(s))

## 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

## Completion date

31/12/2000

# Eligibility

## Key inclusion criteria

Consenting pregnant women at booking.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

## 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

United Kingdom

England

Gambia

## Study participating centre

MRC Human Nutrition Research  
Cambridge

United Kingdom  
CB1 9NL

## Sponsor information

### Organisation

Medical Research Council (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

### 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?
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<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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025 11/11/2025	No	Yes