

Calcium requirements of pregnant women in The Gambia

Submission date 11/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/11/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/06/2024	Condition category 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

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

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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?
Results article	results	01/03/2006		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	follow-up study results	01/09/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	follow-up on blood pressure and growth	18/04/2024	11/06/2024	Yes	No