

The Bakary Dibba Study (BDS): Effect of calcium supplementation on growth and bone mineral accretion in Gambian children accustomed to a low calcium diet

| | | |
|--|---|--|
| Submission date 02/08/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 27/09/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 10/09/2015 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Rural Gambian children have poor growth, delayed puberty, a low bone mineral content, and a very low calcium intake. In this study we are investigating the short and long term effects of calcium supplementation.

Who can participate?

160 children (80 boys, 80 girls) aged 8-12 years old, living in the village of Keneba, in the West Kiang district of The Gambia.

What does the study involve?

Participants are randomly allocated to receive either calcium supplements or matched placebo (dummy) tablets five days a week for a year. We will collect blood and urine samples and measure dietary intake, bone minerals, growth, weight and height and body composition.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

The Elsie Widdowson Laboratory (UK).

When is the study starting and how long is it expected to run for?

January 1995 to December 2012.

Who is funding the study?

Medical Research Council (UK).

Who is the main contact?
Dr Ann Prentice
ann.prentice@mrc-hnr.cam.ac.uk

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
+44 (0)122 342 6356
ann.prentice@mrc-hnr.cam.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Short and long term effects of a randomised placebo-controlled calcium supplementation study in Gambian children aged 8-12 years accustomed to a low calcium diet

Acronym
BDS

Study objectives
An increase in calcium intake by pre-pubertal children accustomed to a low calcium diet will increase growth and bone mineral accretion

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the joint MRC / Gambian Government ethics committee in 1994, ref no SCC 605

Study design

Randomised double-blind single-centre placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoporosis

Interventions

Participants were stratified by sex and randomly assigned to receive a calcium supplement or placebo. The randomisation procedure was conducted by a member of staff in Cambridge UK who was not involved in the data collection. The participants and the field and laboratory staff have remained unaware of the assignments throughout the study.

Children were selected in descending age order until the target numbers were achieved. Four children started the study each week to allow recruitment to be spread over a calendar year. Assignment to group was by a randomised permuted block of four to ensure that an equal number of participants was allocated to the calcium and placebo groups each week, to minimise the potential for seasonal confounding.

The calcium supplement consisted of two chewable calcium carbonate tablets (Calcichew®; Shire Pharmaceuticals Ltd, Andover, UK and Nycomed Pharma AS, Oslo) containing 500 mg elemental calcium/tablet. The placebo consisted of similar tablets, produced by the manufacturer of the calcium tablets.

Each participant received either the calcium supplement or the placebo for 5 days each week for 12 months, starting the week after baseline measurements were taken. The tablets were dispensed to the participants at a centrally located building in the village and were consumed in the early evenings under strict supervision.

Follow-up measurements were made 12 and 24 months after the withdrawal of the supplement, and continue to be made regularly throughout late childhood, adolescence and early adulthood. For girls who have started a family, measurements are made during and after lactation.

Intervention Type

Supplement

Primary outcome(s)

1. Bone mineral status measures [initially forearm single photon absorptiometry (SPA), then whole-body and regional dual energy X-ray absorptiometry (DXA)] at 0, 12, 24, 36 months and regular intervals to adulthood
2. Anthropometry (height, weight, mid upper arm circumference, triceps skinfold) at 0, 12, 24, 36 months and regular intervals to adulthood

Key secondary outcome(s)

1. Biochemical markers of calcium and bone metabolism measured in blood and urine at 0, 12, 24, 36 months and regular intervals to adulthood
2. Body composition measures (whole-body DXA) from 36 months to adulthood

3. Radial and tibial bone and muscle measures by peripheral quantitative computed tomography (pQCT) in early adulthood

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Children aged 8-12 years old living in the rural village of Keneba, West Kiang, The Gambia.
2. Healthy, with no history of any medical condition known to affect calcium or bone metabolism
3. No recent fracture
4. Non-consumer of alcohol, antacids, calcium or other nutritional supplements
5. Non-smokers
6. Girls not on contraceptive pills

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

12 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

United Kingdom

England

Gambia

Study participating centre
MRC Human Nutrition Research
Cambridge
United Kingdom
CB1 9NL

Sponsor information

Organisation
MRC Human Nutrition Research (UK)

ROR
<https://ror.org/050pqs331>

Funder(s)

Funder type
Research council

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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/02/2000 | | Yes | No |
| Results article | results | 01/11/2012 | | Yes | No |
| Results article | results | 01/09/2014 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |