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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

Registration date
27/09/2011

Overall study status
Completed

Last Edited
10/09/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 moneral 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
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 measure
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

Secondary outcome measures
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 aldulthood

Overall study start date
01/01/1995

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

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
80 boys and 80 girls

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
England

Gambia

United Kingdom

Study participating centre
MRC Human Nutrition Research
Cambridge
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Sponsor information

Organisation
MRC Human Nutrition Research (UK)

Sponsor details
Elsie Widdowson Laboratory
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Sponsor type
Research council

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

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	01/02/2000		Yes	No
Results article	results	01/11/2012		Yes	No
Results article	results	01/09/2014		Yes	No