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Gambian bone and muscle ageing study

Submission date 09/06/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2019	**Overall study status** Completed	
Last Edited 03/07/2025	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Musculoskeletal diseases are diseases of the bones, muscles and their attachments (e.g. joints and ligaments). They form a major part of the current global non-communicable (not caused by infections) disease burden. By 2050, the vast majority of the world's ageing population will live in low- and middle-income countries. There is very little information about musculoskeletal diseases from countries in sub-Sarahan Africa. This study is investigating men and women from a poor, subsistence farming community of The Gambia, West Africa. The study is designed to measure changes in bone and muscle health using state of the art techniques and identify possible ways of preventing bone and muscle loss as people get older, and the accompanying risk of falls and fractures which lead to poor health, disability and premature deaths.

Who can participate?
Men and women aged 40 and over living in villages in the Kiang West area of The Gambia

What does the study involve?
Participants are invited to undergo measurements both in the MRC research facilities in The Gambia and whilst they are at home. After measurements have been made at the start of the study they are then seen every 1.5-2 years for follow-up measurements. The data collected includes measurements of bone and muscle strength, hormones and metabolites in urine and blood samples, dietary intake, and blood pressure. Questionnaires are used to obtain information on health, lifestyle, musculoskeletal pain, socioeconomic status, physical activity and reproductive history.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants, other than participation in research aimed at improving health and informing public health nutrition policy in The Gambia and other countries. Participants who have results which may be clinically relevant and suggest previously undiagnosed health problems are referred to the study physician or nurse for initial follow up and then decisions are taken as to whether treatment or further investigation is needed. Ultimately, the findings from this study will contribute to the understanding of musculoskeletal health in populations transitioning from traditional to more western lifestyles. The results are also compared with those obtained from studies of older people in the UK.

Where is the study run from?
The study is being run by the Medical Research Council and takes place in rural villages in The Gambia, West Africa

When is the study starting and how long is it expected to run for?
April 2010 to December 2023

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Kate Ward

Contact information

Type(s)
Scientific

Contact name
Dr Kate Ward

ORCID ID
https://orcid.org/0000-0001-7034-6750

Contact details
MRC Lifecourse Epidemiology
University of Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)2380 777624
kw@mrc.soton.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Gambian Bone and Muscle Ageing Study (GamBAS): a longitudinal observational study in men and women in rural Gambia

Acronym
GamBAS

Study objectives
To characterise changes in bone and muscle outcomes and to identify possible preventative strategies for fracture and sarcopenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2010, Medical Research Council/Gambian Government Joint Ethics Committee (Clo MRC Laboratories, Fajara, P.0. Box 273, Banjul, The Gambia, West Africa; +220-4495919 or 4496 513; +220-4495442-6 ext. 2308), ref: 1222.

Study design
Prospective longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Musculoskeletal health

Interventions
Measurements are made at baseline and follow-up every 1.5-2 years.

Methods include bone imaging (DXA and pQCT), muscle strength (jumping mechanography, grip strength), anthropometry, blood and urine biochemistry, blood pressure, and dietary intake. Questionnaires to obtain information on health, lifestyle, physical activity, socio-economic status, musculoskeletal pain, reproductive history.

Intervention Type

Other

Primary outcome measure
1. Bone mineral content (BMC) is measured using DXA measurements at baseline and follow-ups.
2. Areal bone mineral density (BMD) is measured using DXA at baseline and follow-ups.
3. Bone area is measured using DXA at baseline and follow-ups.
4. BMC is measured using peripheral quantitative CT (pQCT) at baseline and follow-ups.
5. Volumetric BMD is measured using pQCT at baseline and follow-ups.

Secondary outcome measures
1. Bone shape and size by DXA and pQCT.
2. Muscle force/ strength Hand dynamometry for grip force: muscle force/ strength
3. Lateral vertebral assessment using DXA at baseline and follow-ups.
4. Regional and total fat and lean mass are measured using DXA at baseline and follow-ups.
5. Muscle 'density' and area are measured using pQCT at baseline and follow-ups.
6. Height (standing and sitting), demi-span and other limb dimensions, weight, mid-upper arm circumference (MUAC) and 4 skinfolds are measured at baseline and follow-ups.
7. Standing, sitting and lying blood pressure is measured at baseline and follow-ups.
8. Fasting blood, 2-h fasting urine, 24-h urine: including for markers of calcium, phosphate and vitamin D metabolism, bone metabolism, liver and kidney function, clinical chemistry, sex hormones are measured at baseline and follow-ups.
9. Dietary assessment is conducted at baseline and follow-ups.

Overall study start date
01/04/2010

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Men and women aged 40 years and above
2. Able to give informed consent

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
40 Years

Sex
Both

Target number of participants

Stratified sampling to ensure recruitment of equal numbers of men and women in each of eight, 5-year age bands: 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75 years and over; 240 women and 240 men, totalling 480 participants.

Total final enrolment
488

Key exclusion criteria
1. Pregnant or lactating women
2. Individuals deemed too physically frail or incapable, due to existing disability or chronic illness to attend for measurements

Date of first enrolment
17/10/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Gambia

Study participating centre
Kiang West, Lower River Division
Gambia
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Sponsor information

Organisation
Medical Research Council

Sponsor details
14th Floor
One Kemble Street
London
United Kingdom
WC2B 4AN
+44 (0)1793 416 200
corporate@headoffice.mrc.ac.uk

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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
Papers from baseline and first follow up are in preparation.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	baseline data	31/08/2017	11/06/2019	Yes	No
Abstract results		26/10/2021	03/07/2025	No	No

Results article	Sex-specific associations between cardiovascular risk factors and physical function	08/11/2022	03/07/2025	Yes	No
Results article	Vertebral fracture prevalence and risk factors for fracture	07/11/2024	03/07/2025	Yes	No