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Documenting the changes in vertebral shape as children grow

Submission date
24/04/2023

Recruitment status
No longer recruiting

Registration date
24/05/2023

Overall study status
Completed

Last Edited
05/04/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The researchers' long-term goal is to improve the diagnosis and treatment of childhood osteoporosis by improving the detection of vertebral fractures (VF). To achieve this, they must understand the natural change in shape and height of vertebral bodies that occurs in healthy growing children.
Osteoporosis is thinning of the bones. There are over 25 disorders and well over 20 drugs associated with childhood osteoporosis, all predisposing affected children to VF, pain and deformity. Furthermore, 40% of an adult's total bone mass builds up during adolescence, so an adolescent with osteoporosis, if untreated, is likely to become an adult with osteoporosis. Early detection and treatment are important to prevent fracture and deformity.
Dual-energy x-ray absorptiometry (DXA, pronounced "dexa"), which measures bone mineral density (BMD), cannot reliably tell us which children will fracture because not all children with low BMD will fracture, while some will fracture even with normal BMD. Therefore, the International Society for Clinical Densitometry has said that the diagnosis of childhood osteoporosis should be based on the presence of fractures rather than on BMD. This highlights the importance of identifying VF in children.
Because DXA only has a low-radiation dose, the researchers will use DXA to document the normal change in vertebral shape that occurs in healthy children, so that they can more easily recognise the difference in shape caused by VF and therefore improve diagnosis and treatment of childhood osteoporosis.

Who can participate?
Healthy children from schools in Birmingham and Sheffield including girls aged 7, 8, 11 and 12 years old and boys aged 7, 8, 13 and 14 years old.

What does the study involve?
The researchers will explain the study to interested children and their parents. If they give their consent, then they will arrange for the child to attend the Radiology Department at the Children's Hospitals in Sheffield and Birmingham to have a DXA scan. The total scan time will not be more than 10 minutes and will usually be about 5 minutes. After the scan, the researchers will ask each

child to answer a short questionnaire about their experience. They will give each child a copy of their scan and then they will be free to leave. The child will have no further involvement in the study.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part. The researchers anticipate that all children are healthy and that their scans will therefore be normal. All scans will be looked at by the study lead Professor Amaka Offiah and if an abnormality is detected, the child's GP will be contacted to arrange further investigations for the child. A radiation physicist has confirmed that taking part in the study exposes each child to an extremely small increased lifetime risk of developing cancer, equivalent to the risk of a few weeks' natural UK background radiation.

Where is the study run from?
Sheffield Children's NHS Foundation Trust (UK) and the University of Sheffield (UK). Birmingham Women's and Children's NHS Foundation Trust (UK) is also participating.

When is the study starting and how long is it expected to run for?
January 2019 to January 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Prof. Amaka C Offiah, amaka.offiah@nhs.net

Contact information

Type(s)
Scientific

Contact name
Prof Amaka Offiah

ORCID ID
https://orcid.org/0000-0001-8991-5036

Contact details
Room 3, Damer Street Building
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 271 7557
amaka.offiah@nhs.net

Type(s)
Scientific

Contact name
Dr Nicola Crabtree

ORCID ID
https://orcid.org/0000-0001-6729-5841

Contact details
Birmingham Women's and Children's NHS Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH
+44 (0)121 333 8517
nicola.crabtree@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315446

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55277, IRAS 315446

Study information

Scientific Title
Developing normative standards for vertebral morphology in children: a feasibility study

Study objectives
It is feasible to recruit a sufficient number of children to develop an atlas of normal vertebral morphology in boys and girls from 5 to <18 years old.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2023 Cambridge East REC (2nd Floor Equinox House, Health Research Authority, NG2 4LA, UK; +44 (0)20 7104 8096; CambridgeEastREC@hra.nhs.uk), ref: 23/EE/0043

Study design
Observational; Design type: Cross-sectional

Primary study design
Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Vertebral morphology in children

Interventions
70 healthy growing children (17 girls and 18 boys aged 7 to 8 years, 18 girls aged 11 to 12 years and 17 boys aged 13 to 14 years) will be recruited from schools in Sheffield and Birmingham. Researchers will visit the schools to present and promote the study at assemblies, open days and parents meetings. Posters will also be displayed in the schools. Subsequently, older children (11 to 14 years) who express interest in participating will receive study packs containing volunteer information sheets and parental consent/volunteer assent forms from their form teacher. Signed consent/assent forms will then be handed in to the form teachers. For younger children (7 to 8 years), the study packs will be handed to teachers to give directly to parents, who will then sign and return them to the teachers.

The researchers will recruit two children aged 11 to 14, two children aged 7 to 8 and two parents of children aged 7 to 8 years to assist with recruitment within their schools. They will also help with developing the volunteer information sheets, consent/assent forms and advertising /educational materials.

Contact details will be collected on the consent/assent forms. As part of the consent pack, parents will complete a health questionnaire with their child to ensure that they do not meet any of the exclusion criteria. Researchers will collect the signed forms from the schools and hand these over to the local radiology department receptionists; Sheffield Children's Hospital for children from Sheffield schools and Birmingham Children's Hospital for children from Birmingham schools. The receptionists will contact the parents/guardians to arrange a suitable appointment time and date to attend the local radiology department.

Each child recruited will attend the radiology department for a single visit with their parent /guardian. During this visit, each child will have a whole body DXA (low dose x-ray) scan, a DXA of their backbones and a DXA scan of their left hand. The child's height and weight will also be recorded.

These images will be reviewed by the researchers and the backbone measured. By looking at the range of different measurements in healthy children of the same age we can understand the degree of variability. The more variability there is, the more children we will need to recruit for a future, larger study. The results from the 70 children who participate will also be used in the full study.

Each participant will complete a self-assessed pubertal score during their visit.

The researchers will ask families for their feedback on the process at the end of their visit. They will analyse this feedback to make sure it is acceptable to both children and parents. They will use this feedback to improve the process for the future study.

Each child who participates will receive a copy of their DXA scan plus a £10 Amazon.co.uk voucher. A school assembly will be given including information on optimising bone health.

The results will be disseminated through the schools with the volunteer children and parents taking a lead on this. The researchers will publish the results on the website of Sheffield Children's Hospital and present the results at national and international research meetings. They will also publish the results in a scientific journal.

We estimate that the entire study will take 15 months with participant recruitment and imaging taking place over a period of 6 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Participant acceptance of attending hospital, measured using a non-validated questionnaire on Day 1
2. Recruitment rate, defined as the number of participants recruited per month over the 7-month recruitment period

Key secondary outcome(s))
Variability of vertebral morphometry in young children measured using analysis of variance for differences in anterior, middle and posterior vertebral heights by age and sex on Day 1

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Healthy growing children from school in Sheffield and Birmingham
2. 35 children (17 girls) aged 7 to 8 years, 18 girls aged 11 to 12 years and 17 boys aged 13 to 14 years. Ages have been selected to represent the periods of rapid childhood growth by sex

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
14 years

Sex

All

Key exclusion criteria
1. Ongoing chronic disease
2. Ongoing long-term steroid medication
3. Scoliosis or significant kyphosis
4. History (within preceding 3 years) of road traffic accident
5. History (within preceding 3 years) of back pain/stiffness (particularly morning stiffness)
6. History (within preceding 3 years) of investigation for unexplained fever, malaise, aches/pains
7. Abnormal VFA identified during the study (ACO will review all images to confirm normality. Assent/consent will be obtained from volunteers and parents/guardians to inform the child's GP should any abnormality be detected, in order for the child to be appropriately referred and investigated)

Date of first enrolment
01/02/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NW

Sponsor information

Organisation

Sheffield Children's NHS Foundation Trust

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

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?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes