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Relating results from ultrasounds of the hip and spine to X-ray scans for measuring bone health

Submission date
10/02/2020

Recruitment status
No longer recruiting

Registration date
02/03/2020

Overall study status
Completed

Last Edited
06/12/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ultrasound of the lumbar spine and proximal femur can be used to assess bone mass and quality. The aim of the study is to test how acceptable the ultrasound is to patients, and how easy the tests are to perform, and to compare ultrasound with the results of conventional DXA (the gold standard test for osteoporosis).

Who can participate?
Patients aged 30 to 80 attending for a DXA scan as part of routine clinical care

What does the study involve?
Having an ultrasound of the hip and lower back at the same time as participants attend for a DXA scan requested by their doctor.

What are the possible benefits and risks of participating?
Participants will help researchers understand whether the tool being tested (ultrasound) works as well as the currently used test – DXA – in identifying people with osteoporosis. This is helpful as DXA scanners are not available everywhere, and ultrasound scanners may be more affordable and accessible. There are no risks associated with this study.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2017 to December 2021 (updated 01/12/2020, previously: December 2020)

Who is funding the study?
National Research Council of Italy

Who is the main contact?
Dr Elaine Dennison
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
230385

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 38414, IRAS 230385

Study information

Scientific Title
ECHographic technologies for bone fracture risk assessments and better OSteoporosis diagnoses (ECHOS)

Acronym
ECHOS

Study objectives
This application seeks permission to measure ultrasound of the lumbar spine and proximal femur to assess bone mass and quality and compare it to dual-energy X-ray absorptiometry (DXA) measurements obtained at the same time and as part of usual clinical care in those

participants who give consent. The aim of the study is to test how acceptable the ultrasound is to patients, and how easy the tests are to perform, and to compare results of conventional DXA (the gold standard test for osteoporosis) with ultrasound.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2018, West of Scotland REC 4 (Research Ethics Clinical Research and Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow G3 8SJ, UK (Formerly Yorkhill Childrens Hospital); Tel: +44 (0)141 232 1808; Email: WoSREC4@ggc.scot.nhs.uk), REC ref: 18/WS/0102

Study design
Non-randomised; Interventional; Design type: Diagnosis, Imaging

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
All patients who are referred to the Osteoporosis centre for DXA testing at Southampton General Hospital will be considered for this study. An information sheet will be sent out with their appointment letter, detailing the study. Those patients who agree will have ultrasound scans performed at the same time as their DXA scan. This is expected to take about 5-10 minutes in total.

Intervention Type
Other

Primary outcome measure
The assessment of correlation degree and diagnostic agreement between the new ultrasound method for osteoporosis diagnosis and DXA outcome, collected at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2017

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Attending for DXA scan as part of routine clinical care
2. Both women and men
3. All ethnicities
4. Age range from 30 to 80 years
5. Body mass index (BMI) < 40 kg/m2
6. Absence of significant walking impairment
7. Medical prescription for a spinal and/or femoral DXA
8. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 5000; UK Sample Size: 1000

Total final enrolment
4307

Key exclusion criteria
1. Must be able to understand information sheet and give informed consent
2. Significant walking impairment
3. BMI > 40 kg/m2

Date of first enrolment
18/12/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
National Research Council of Italy

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation

Intention to publish date
31/12/2022

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?
Protocol file	version 1	01/04/2022	24/08/2022	No	No
Results article	primary results to assess the diagnostic accuracy of Radiofrequency Echographic Multi Spectrometry (REMS) technology with respect to DXA	24/12/2022	06/12/2022	Yes	No
HRA research summary			28/06/2023	No	No