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	Prospectively registered		
		[X] Protocol		
Registration date 02/03/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 06/12/2022	Condition category Musculoskeletal Diseases	☐ 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 emd@mrc.soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Elaine Dennison

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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/m^2

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

Sponsor details

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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?
<u>Protocol</u> <u>file</u>	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