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PHOENIX-Feasibility: picking up hidden osteoporosis effectively during normal CT imaging without additional x-rays

Submission date
15/01/2019

Recruitment status
No longer recruiting

Registration date
15/08/2019

Overall study status
Completed

Last Edited
29/07/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis is a condition that weakens bones, making them fragile and more likely to break. It is a condition that develops slowly over several years and is often only diagnosed when a minor fall or sudden impact causes a bone break (or fracture). Osteoporosis particularly affects the spine and hips, resulting in breaks of the bone in these areas. Whilst treatment of osteoporosis is now quite straightforward, detection is difficult. In the UK, osteoporosis causes 200,000 fractures of the spine yearly in women and men. The pain of a small spine fracture can feel like ordinary backache, and as a result patients are often left undiagnosed, so many small fractures are common. This eventually leads to poorer mobility and increased pain for the sufferer. The aim of this study is to find out whether it is possible to identify osteoporosis earlier, leading to improved treatment and better outcomes. To do this the researchers will be looking at special scans called CT scans (computerised tomography) that patients are already having for various reasons, and using some new software that has been developed to make more accurate diagnosis of osteoporosis and bone fractures. A CT scan uses x-rays and a computer to create images of the inside of the body; two million are performed each year in the UK, often for abdominal or pelvic problems. In this study, CT images are reviewed using a new software to identify osteoporosis enabling early treatment and potentially preventing future fractures. This new technology makes it simple to measure a patient’s bone density quickly and identify vertebral fractures from CT images of a patient's torso or pelvis. Bone density measurements of the spine and hips are performed on images acquired from any CT scanner. This study is a feasibility study to see if it is realistic to develop into a national trial, so the researchers will be looking at how well they can recruit participants to the study, and as they hope to follow up with a questionnaire after one year, they will also be looking at how many people stay in the study, or drop out.

Who can participate?
Women aged 65 - 90 and men aged 75 - 90 years who are undergoing a CT scan that includes the pelvis

What does the study involve?
If someone is attending a CT Department for a scan in a participating hospital and is eligible to be part of the study (that is, within the correct age range and having a scan that includes the pelvis), they will be approached by a member of the research team at the local hospital and asked if they would like to be part of the study. If they are interested in being part of the study the patient will be asked to complete a Bone Health Questionnaire and sign a consent form. The patient will also be asked for their contact details so that the researchers can post out a questionnaire in about 2 months' time, and later at about 1 year. The answers of the Bone Health Questionnaire will be used to calculate the chance of that patient breaking a bone during the next 10 years. If the answers suggest an increased risk, they will be randomly allocated to one of four study groups. In all four groups, bone density is measured and the scans are studied for evidence of small fractures; in some cases this will happen immediately and in others in 12 months' time (there will not be a difference in long-term outcomes for the patient if they are in the group with delayed review of the scan). The groups will be chosen at random (like tossing a coin to make a decision) and NOT by the doctor. If answers suggest that the chances of breaking a bone are low, there will be no need to check bone health straight away. Once the CT scans are looked at by the specialist team in Cambridge, a report will be sent to GPs with results and guidance as to any treatment. Two questionnaires are sent out to participants – one after about 2 months, and one at one year. These will ask about any medication that may be prescribed for bone health and how participants are managing in their day to day life; they should take about 15 minutes to complete. A small number of patients will be asked if they would agree to telling us about their experience of the study; this can be by face to face discussion, or over the phone.

What are the possible benefits and risks of participating?
Possible benefits are that patients may receive earlier diagnosis and treatment of osteoporosis. There are no risks to being part of this study.

Where is the study run from?
The study is run jointly by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge. Scans will be looked at in Cambridge, and all co-ordination of the study will be from there. There are other sites participating in this study: Addenbrooke's Hospital, Peterborough City Hospital, Lister Hospital, West Suffolk Hospital and Bedford Hospital.

When is the study starting and how long is it expected to run for?
September 2019 to December 2024

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

Who is the main contact?
Karen Willoughby
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Study website
http://www.med.cam.ac.uk/poole/phoenix/

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PB-PG-0816-2007; CPMS: 41112

Study information

Scientific Title
PHOENIX-f: a feasibility study for early identification of vertebral fractures and osteoporosis by opportunistically using CT scans undertaken for other purposes

Acronym
PHOENIX-f

Study objectives
It is hypothesised there will be value in early diagnosis and treatment of osteoporosis, through fractures prevented, societal and social burden and reduced health costs. The current usual care for case-finding osteoporosis in older people is for the GP to ask their patient to complete a FRAX questionnaire. The responses to these 11 questions regarding fracture risk factors are then entered by the GP into an online calculator which indicates whether a DXA scan should be requested. Uptake of case finding is low and there is no national mandate for screening. High-risk patients are referred for a DXA scan and treatment is offered if the bone mineral density (BMD) is low and/or fracture risk sufficiently high. Vertebral fractures are rarely detected in usual care even though they (alongside hip fractures) cause the biggest burden to patients and the health service. The expectation is that targeted screening will improve upon usual care and appropriately increase the diagnostic rate.

There are several reasons for opportunistic osteoporosis screening during a CT scan:
1. CT attenders are a high-risk population; >30% of these older adults have undiagnosed vertebral fractures or osteoporosis that can be effectively treated once identified
2. The PHOENIX pathway allows us to diagnose osteoporosis on scans already done, without additional x-rays/hospital visits
3. Opportunistic case-finding is recommended by NICE
4. Screening is effective at reducing hip fractures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/07/2019, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)20 7104 8096; Email: nrescommittee.eastofengland-cambridgeeast@nhs.net), REC ref: 19/EE/0176

Study design
Randomised controlled non-blinded multi-centre feasibility study

Primary study design
Interventional

Secondary study design
Feasibility study for future intended clinical randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
Current intervention:
The intervention is a FRAX questionnaire and a review of CT scans repurposed to look for vertebral fractures and early osteoporosis using software developed for the diagnosis of osteoporosis and bone fractures. In Group 1, GPs will immediately be informed of the analysis, in Group 2 GPs will receive only FRAX calculation results, in Group 3 no results will be communicated with GPs and in Group 4, a referral to an Osteoporosis specialist will be made, rather than sending the results to the GP. To avoid any disadvantage, all CT scans of participating individuals will be analysed and results sent to GPs after one year if they are in Groups 2 and 3. Additionally, those on treatment after 1 year will be compared between Group 1 and Group 4.

Previous intervention:
Intervention is FRAX questionnaire and review of CT scans repurposed to look at for vertebral fractures and early osteoporosis using software. GPs will be informed of analysis immediately in Group 1, in Group 2 GP will receive only FRAX calculation results and in group 3 no results will be communicated. To avoid any disadvantage, all CT scans of participating individuals will be analysed and results sent after one year to GPs if they are in Groups 2 & 3.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study in 10 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up one year after recruitment

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2018

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Attend one of five participating radiology departments
2. Volunteers able to provide informed consent
3. Women aged ≥65 - 90 and men aged ≥75 – 90 years inclusive
4. Attending for CT, for any clinical reason, where the spine and/or hips are visible in the scan images

Participant type(s)

Patient

Age group
Adult

Lower age limit
65 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 625; UK Sample Size: 625

Key exclusion criteria
1. Aged > 90
2. Bilateral metalwork in hips
3. Unable to provide valid consent
4. Known to be receiving prescription treatment for osteoporosis other than calcium/vitamin D (i.e. bisphosphonate drug, strontium ranelate, denosumab, raloxifene or teriparatide)
5. Prone CT scan

Date of first enrolment
29/10/2019

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

North West Anglia NHS Trust
Hinchingbrooke Hospital
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
East & N Herts NHS Trust
Lister Hospital
Stevena
United Kingdom
SG1 4AB

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Bury St Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Bedford Hospital
Kempston Rd
Bedford
United Kingdom
MK42 9DJ

Sponsor information

Organisation
Cambridge University NHS Foundation Trust

Sponsor details
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type

Hospital/treatment centre

Website
https://www.cuh.nhs.uk/addenbrookes-hospital

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
On study completion the data will be analysed and report submitted to the funding body to indicate feasibility of progressing to a full trial.

Intention to publish date
30/11/2025

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 V1.2	01/07/2019	15/08/2019	No	No
Protocol article		24/05/2022	27/05/2022	Yes	No
HRA research summary			28/06/2023	No	No