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Supine and erect pelvis radiographs: a pilot study

Submission date
05/02/2018

Recruitment status
No longer recruiting

Registration date
23/02/2018

Overall study status
Completed

Last Edited
18/05/2021

Condition category
Musculoskeletal Diseases

[_] 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
X-ray images are a primary tool in investigating diseases of the hip joint. The reproducibility of this examination is especially important for diagnosis and monitoring of arthritis and following hip replacement surgery. Pelvis x-rays are routinely performed with the patient lying down, however some studies have shown that standing is more effective, demonstrating abnormalities taking into consideration the effect of load. Previous research has demonstrated that the pelvis tilts with different postures (i.e. lying, sitting, standing) and understanding these changes to the resultant x-ray image is vital. Importantly, no research has considered the radiation dose implications of changing from supine to standing technique. The aim of this study is to examine the differences in diagnostic markers and radiation dose between the different positions in three phases.

Who can participate?
Adults aged 18 and older who are referred for a pelvis or hip x-ray and are able to stand unaided.

What does the study involve?
This study includes two phases. In phase, participants have their height, weight and trunk diameter/circumference measured whilst erect and supine (laying on their back). They have the standard supine pelvis X-ray performed. For phase two, an anthropomorphic phantom will then be utilised to establish the imaging protocol to provide suitable quality images with the lowest radiation dose. The third phase of the study will then recruit more participants who have been referred for pelvis or hip x-rays and they will have their imaging performed in both lying and standing positions. The recruitment and refusal rates are used to inform future study design and confirm sample size. The data will assist in determining variation in radiation dose, anatomical measures for hip disease and anatomy between positions.

What are the possible benefits and risks of participating?
No direct benefit will be received by participants in the study. There are no anticipated risks associated with participation.

Where is the study run from?
Pinderfields Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2017 to May 2018

Who is funding the study?
Society and College of Radiographers (SCoR) (UK)

Who is the main contact?
Miss Martine Harris (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
36407

Study information

Scientific Title
A pilot study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic quality

Study objectives
This feasibility study aims to determine if patient posture (erect or supine) has an effect on soft tissue anatomy (body shape/size). We want to identify the implications of postural changes on radiation dose and image quality for X-Ray examination.

The study objectives are to:
1. Identify radiation dose and image quality metrics
2. Determine the scope of a future research study proposal, including trial procedures, imaging protocols and patient information
3. Identify the recruitment and refusal rates to such research

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - South Yorkshire Research Ethics Committee, 14/12/2017, ref: 17/YH/0363

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

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Other; UKCRC code/ Disease: Musculoskeletal/ Other osteopathies

Interventions
In phase 1 the participants have measures undertaken in the supine and erect position but just have the standard supine pelvis X-Ray performed.

During phase 3 a new cohort of participants are recruited to have measures and an additional pelvis X-Ray taken in the erect position in addition to the standard supine pelvis X-Ray.

There is no follow-up post intervention in either phase.

Intervention Type
Other

Primary outcome(s)
Difference in abdominal soft tissue thickness, measured by a researcher with a tape measure (in cm) in supine and erect position at baseline (incorporating phase 1 & 3 data).

Key secondary outcome(s))
1. Difference in abdominal circumference, measured (in cm) in supine and erect position at baseline (incorporating phase 1 & 3 data)
2. BMI will be calculated using height and weight measurements obtained at baseline (incorporating phase 1 & 3 data).
3. Difference in radiation dose between X-Rays performed in supine and erect position as

measured by dose area product (DAP) at baseline (phase 3).
4. Image quality variation between supine and erect X-Rays performed at baseline will be measured using a validated psychometric scale (phase 3).

Completion date
30/09/2018

Eligibility

Key inclusion criteria
Phase 1:
1. Patients over the age of 18 who attend for x-ray of the hip or pelvis from a MYH OP clinic or their GP
2. Able to stand unaided
3. Have not had lower limb surgery in the last six months
4. Able to provide written informed consent.

Phase 3:
1. Patients who over the age of 18 attend for x-ray of the hip or pelvis from a MYH OP or their GP
2. Not pregnant
3. Able to provide written informed consent
4. Able to stand unaided
5. Have not had recent trauma or a pelvic x-ray or pelvic radiotherapy in the preceding 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

Key exclusion criteria
Patients who are under the age of 18, pregnant, have undergone lower limb surgery within the previous six months or are unable to provide written informed consent will be excluded from the study. A further exclusion will be related to patients who are unable to stand unaided, as the ability to weight bear would be a key component in performance of an x-ray in the erect posture.

Date of first enrolment
15/01/2018

Date of final enrolment
12/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pinderfields Hospital
Rowan House
Wakefield
United Kingdom
WF1 4DG

Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Research council

Funder Name
Society and College of Radiographers (SCoR)

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			28/06/2023	No	No
Participant information sheet	version V2	29/11/2017	23/02/2018	No	Yes
Participant information sheet	version V2	29/11/2017	23/02/2018	No	Yes
Protocol file	version v1.4	05/12/2017	23/02/2018	No	No