A pilot study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic quality (SEPRAIDD)

Study Protocol

The Mid Yorkshire Hospitals NHS Trust

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Abbreviations and Acronyms

AEC	Automatic exposure control
BMI	Body mass index
DAP	Dose area product
ED	Effective dose
EI	Exposure index
ESD	Entrance surface dose
GCP	Good Clinical Practice
IRMER	Ionising Radiation (Medical Exposure) Regulations 2000
kV	Kilovolts
mAs	Milliamps per second
MYH	Mid Yorkshire Hospitals NHS Trust
OA	Osteoarthritis
PCMXC	PC program for x-ray Monte Carlo
SID	Source image distance

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A pilot study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Summary

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.

This pilot study will examine differences in diagnostic markers and radiation dose between the different positions in three phases. To estimate the change in patient soft tissue anatomy between supine and erect positions in phase one we will recruit 180 patients referred for pelvis or hip radiographs to have their height, weight and trunk diameter/circumference measured whilst erect and supine. This data will allow modelling of the change in patient body shape between the two projections. 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 60 patients 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 will 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.

A key outcome will be a grant application to determine if patient posture affects the clinical outcomes, in terms of image quality, or the radiation dose received by the patient. The outcomes from this study will support the development of future research which will seek to identify the clinical impact of erect pelvic radiographs in a large scale population.

Background

When evaluating diseases of the hip, clinical history and physical examination are commonly supplemented with radiographic images. Radiography is an essential tool in diagnosis of hip pathologies and is accessible, cheap and results in a relatively low radiation dose being delivered to the patient. Hip radiographs allow the evaluation of abnormal hip anatomy (dysplasia) and pathologies throughout the age spectrum. Hip pain in the younger adult is often related to dysplasia and pain can be symptomatic of impingement.[1] However, it is the evaluation and monitoring of osteoarthritis (OA) which accounts for the greatest utilisation of radiography in the non-trauma setting. As the hip is subject to ongoing wear and tear[2] OA largely affects older people and by 2020 it will be the fourth most common cause of disability in the UK.[3] It is estimated that hip OA is symptomatic in 5-9% of the population, with pain, stiffness, deformity and/or decreased mobility. It has a poor outcome, with a significant number progressing to joint replacement within 5 years. Not all patients with radiographic evidence of OA, likely to be as high as 19%,[4] will have symptoms but it is suggested that half will be suffering. Radiographs also support surgical planning, with a need to accurately template anatomy to ensure correct choice of components and location[5]. Siting a replacement within a suboptimal location can increase the risk of dislocation and failure. For these patients ongoing monitoring is required and radiography is performed on a regular basis to check for signs of loosening and failure.

Radiographic diagnosis relies on the identification of often subtle changes but these may be masked by variations in hip alignment as a result of patient positioning[6,7] or anatomical variations which may cause apparent, or true, pelvic anteversion (anterior tilt) or retroversion (posterior tilt).[8,9] Siebenrock et al[10] suggested limits for neutral radiographic pelvic tilt to ensure acceptability, but they did not acknowledge natural variations between persons, but rather took it as a failure of radiographer positioning.

Hip radiographs are traditionally performed with the patient supine, however an assessment of anatomical relationships is required to diagnose and treat musculoskeletal disorders on an individual basis.[6,11] As the hip carries the weight of the body there is potential for these relationships to vary with an erect posture. This has significant relevance with increasing obesity which is known to alter posture. Therefore conforming investigations to potential causality for, or exacerbation of, pain and/or presentation is important. It has been confirmed that pelvic orientation changes between lying, sitting and standing with the pelvis tilting with upright posture. A review by Troelsen[6] found that changes varied from nil to 8^0. Importantly, research studies cannot be compared directly due to variations in population (normal subjects or dysplasia) and measures (AP and/or lateral radiographs or inclinometer). The work by Troelsen confirmed that the change in pelvic tilt can vary between females ($13\text{-}14^0$) and males ($6\text{-}7^0$). The consensus is therefore strong that there is a change in pelvic orientation related to posture and that this change may have significant implications for stability of hip replacements and exacerbation of pain in patients with impingement or OA.

This recognition has led to a number of authors to suggest that radiography should be obtained erect, as pain is often only present during weightbearing.[2,6,12,13] This integrates radiographic technique with symptoms, function and potential hip deformity or pathology. Previous research has predominantly been led by orthopaedic surgeons and has considered the impact of patient

orientation to pelvic tilt,[11,12,13] hip joint space width[7,14,15] or postoperative acetabular version.[5,16,17] Research is severely limited in sample size and has focused on specific patient groups rather than the broader population. Importantly the result of previous research are inconsistent and studies have found the hip joint space to be reduced[7] or unchanged.[15] This therefore presents a limited and conflicting evidence base, with no agreed parameters for positioning.

The inconsistent radiographic technique and centring points have also been highlighted by patient exclusions in orthopaedic research studies because radiographs do not meet pre-determined positional and quality criteria.[12,13,18] Interestingly, issues of radiographic technique were also identified in the 2014 NICE guidelines for hip OA[3] which states that differing radiographic protocols contribute to a lack of robust evidence around their use. Radiography textbooks are also contradictory, resulting in local variation.[19-23] Indeed one textbook suggests flexing a patients' hips and knees slightly to correct for pelvic tilt, a factor unlikely to be appreciated by clinicians, with potential to lead to misinterpretation.[22]

Importantly, no previous study has considered the radiation dose implications of patient posture or defined the standardised positioning required to introduce this as a mainstream investigation. Patient position has potential to influence radiation dose through reduced soft-tissue compression and increased overlying abdominal tissues. This would have significant implications for image quality, which in turn could impact on clinical decision making. National dose reference levels (DRLs) do not exist for erect positioning, a non-standard technique, meaning that there is no parameters for dose in this projection, despite a small number of Trusts already adopting this technique. Interestingly, authors have demonstrated opportunities to reduce radiation dose with increased distance or orientation on digital equipment, but these were only undertaken supine using an anthropomorphic phantom[24,25,26] and have not been translated into clinical practice. As a result this research hopes to develop a patient centred evidence base for the positioning and exposure factors for erect AP pelvis projections.

Key research questions

The key research questions requiring an answer are:

1. Does pelvic radiography performed in the erect position result in an increase in radiation dose to the patient?
2. Does pelvic radiography performed in the erect position demonstrate clinically significant changes in image quality when compared to a supine X-ray image?
3. Are erect pelvic radiographs acceptable to patients in their performance?
4. Would the change impact on service delivery, in terms of examination time?

Aims

This study aims to ensure that X-ray images of the pelvis are performed using evidence based protocols. It will also determine if patient posture (erect or supine) has an effect on radiation dose, image quality and diagnostic measures.

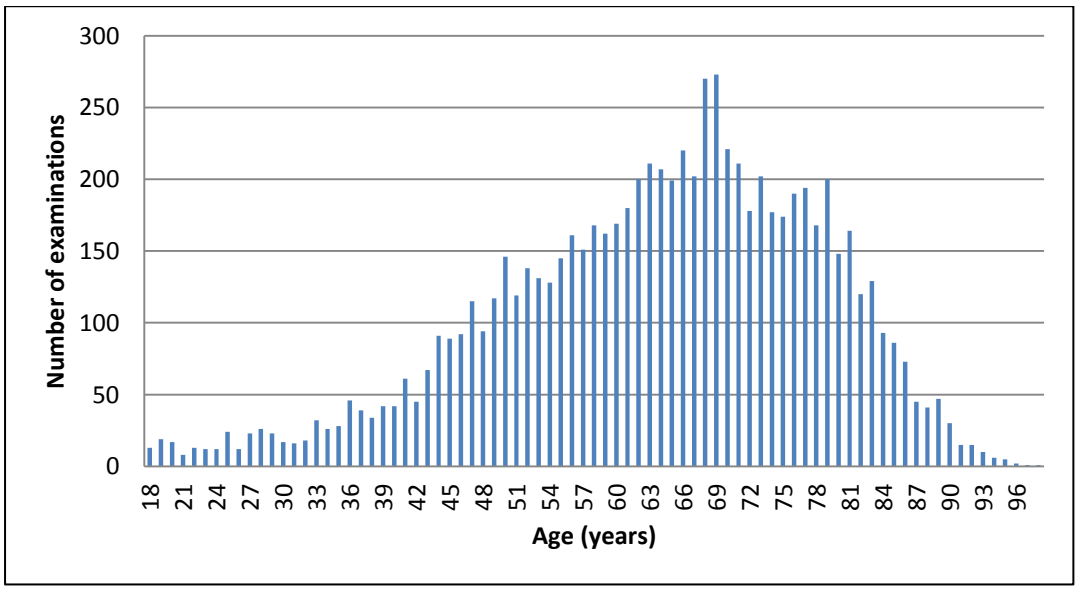
The study objectives are to:

- Develop trial procedures, imaging protocols and patient information for a future study
- Estimate the recruitment rate for a prospective study which will the diagnostic and dose differences between supine and erect pelvic radiographs
- Identify the recruitment and refusal rates to such research.

Study site

A single NHS Trust is being used to control for variations in technique and equipment. Mid Yorkshire Hospitals NHS Trust (MYH) comprises 3 hospital sites, Dewsbury District Hospital, Pinderfields Hospital (Wakefield) and Pontefract Hospital. Almost 8000 adult patients were referred from either their GP or as an outpatient to the Trust radiology department for pelvis or hip radiographs in 2016, including those referred for a hip x-ray where a full pelvic radiograph is performed as standard. The age profile of these patients is demonstrated in Figure 1. This demonstrates that the median age of this patient population is 65, with 80% of all patients being over 50 years in age.

Figure 1: Pelvic radiographs referred by OP or GP by patient age



Method

Phase One: Patient modelling

The initial data collection will focus on ascertaining the patient population and how physical characteristics (body shape) differs between the erect and supine positions. This will be through standardised measures obtained in both positions.

Sample size

A cohort of 180 patients who are attending for radiography of the hip or pelvis from either an outpatient (OP) clinic or their general practitioner (GP) will be recruited. Specifically the study aims to achieve a minimum of 30 patients in each of the following categories:

- Underweight/Normal (BMI<25)
- Overweight (BMI 25-30)
- Obese/Morbidly obese (BMI>30)

Inclusion criteria

All patients who attend for radiographs of the hip or pelvis from a MYH OP clinic or their GP will be eligible for inclusion to the study. It is estimated that there are approximately 60 eligible patients per week attending each hospital site within the study organisation.

Exclusion criteria

Patients who are under the age of 18, pregnant, are unable to stand unaided, 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.

Withdrawal

Any participant can withdraw from the study at any point prior to final data analysis, expected to be 1 month from end of recruitment. Their data will be excluded from the study and records destroyed, however the radiographs will be retained as part of the clinical record.

Recruitment process

Recruitment will take place over a 6-week period to allow for workflow variation and patient refusal. Reasons for patient refusal will be collated to inform a future trial.

A study patient information leaflet (Appendix 1) will be sent with appointment letters for potential recruits from the general practitioner. These patients will be identified by the radiology appointments team at the time of booking an examination. This will also be made available within the orthopaedic clinic to patients attending for an appointment. The information sheet will explain what the study is undertaking and what the research is looking at and explain the risks and benefits of taking part. This will allow time for potential recruits to read the patient information leaflet and, if required, approach the study team prior to being asked for informed consent.

Poster information will also be displayed within the hospital outpatient areas for patients to read prior to attending the radiology department.

When the patient attends the radiology department for their radiographs a member of the radiology team will confirm their eligibility to participate in the study. A GCP trained member of staff who is a fully qualified radiographer who works permanently within the radiology department will then approach the patient, introduce themselves and explain the study and research and what will be required from them to take part within the study. Informed written consent (Appendix 2) will then be gathered from each recruit prior to any data collection.

Data collection

The recruited participant will be asked to change into a gown appropriate to their radiological examination and then taken to a private room (x-ray room) to maintain dignity and privacy. They will then have various measures undertaken by the research team member (see instruction sheet appendix 3).

These will include:

- Height (m)
- Weight (kg)
- Body circumference
- Source-Object Distance (i.e. x-ray tube to patient skin, as a proxy for body diameter)

A small group of radiographers will be trained to undertake the specific study parameters to ensure consistent data collection (Appendix 4). They will then continue with the radiographic examination as requested by the referring clinician.

Data analysis

The data collected will allow modelling of the change in patient body shape between the two projections. Variations in shape between BMI subgroup, gender and age will be assessed. Mean and standard deviations will be calculated if the resultant data are approximately normally distributed and median (ISR) measures will be determined for non-parametric data.

Phase Two: Phantom Experiment

An anthropomorphic phantom of the abdomen and pelvis will be used to investigate the optimal image acquisition protocol based on the anatomical changes identified in phase one. No patients will be recruited for this part of the study.

The outcome of the phantom study will be specific kV and mAs settings or automatic exposure control (AEC) settings for the different techniques and comparison of the phantom dose data with national diagnostic reference levels.

Based on the variation in mean measures between the different position and body habitus in phase one a Kyoto phantom will be physically altered with the addition of appropriately positioned soft tissue density mimicking material. This will enable multiple exposures of the phantom to be made at different distances and exposure factors to ascertain whether automatic exposure devices can be reliably used in both of the patient positions or whether specific exposure charts should be calculated regarding a patient's body habitus.

An example of the acquisition procedure is demonstrated in figure 2 below. The resultant images will be analysed for quality in relation to visualisation of the bony anatomy of the pelvis and hip joint. Based on a previously validated technique[26] radiation dose (entrance surface dose (ESD) and effective dose (ED)) will be calculated using a commercially available computer software system which utilises Monte Carlo code dose simulation (PCMXC). Calculations require the source-object distance, mAs and peak tube potential values (kV) to be entered for each data point.

Figure 2: Anthropomorphic phantom acquisition in erect orientation

Phase Three: Pelvic Radiograph Acquisition

This phase will compare radiographs obtained on the same patient in two different positions, supine and erect. The supine positioning is that which is currently undertaken within the imaging department. The erect positioning technique and acquisition parameters will be informed by the earlier phases of the research.

Sample size

A single arm pilot study is planned with no attempt at this time to undertake sub-group analysis. A minimum of sixty patients will be recruited to this study based on the premise of the future trial demonstrating a 5% difference in pelvic tilt between the 2 projections (95% confidence interval),[27] this exceeds 10% of the potential future trial requirements[28,29] and includes a minimum of 12 participants per subgroup.[30]

The future trial is estimated to require a minimum sample of 474, based on the same calculations. To allow for the inability to perform the erect x-ray, exclusion based on image quality and to enable sub-group analysis, it is planned that the sample recruited would be 800. The subgroup analysis for referral reason will comprise:

1. Young adult with hip pain (18-40)
2. Patient with evidence of hip dysplasia
3. Older adult referred with symptoms or diagnosis of OA
4. Previous hip replacement under monitoring

Inclusion criteria

All patients who attend for general radiography of the hip or pelvis from their general practitioner or outpatient clinic will be eligible for inclusion to the study. It is estimated that there are approximately 60 eligible patients per week attending any one hospital site within the study organisation.

Exclusion criteria

Patients who are under the age of 18, pregnant, have recent trauma or undergone hip or knee surgery within the previous six months or are unable to provide written informed consent will be excluded from the study. Patients who have a pelvic x-ray or pelvic radiotherapy in the preceding 6 months will also be excluded to minimise their radiation exposure. A further exclusion will be related to patients who are unable to stand unaided, as the ability to weight bear is a key component in performance of an x-ray in the erect posture.

Recruitment process

A phase three study patient information leaflet (Appendix 5) will be sent with appointment letters for potential recruits from the general practitioner. These patients will be identified by the radiology appointments team at the time of booking an examination. The information sheet will introduce the study and what the research is looking at and explain the risks and benefits of taking part. This will allow time for potential recruits to read the patient information leaflet and, if required, discuss with family or friends or approach the study team prior to being asked for informed consent.

Poster information will also be displayed within the hospital outpatient areas for patients to read prior to attending the radiology department.

When the patient attends the radiology department for their radiographs a member of the radiology team will confirm their eligibility to participate in the study. A GCP trained member of staff (HCPC registered radiographer who works permanently within the radiology department will then approach the patient, introduce themselves, explain the study and research and what will be required from them to take part within the study. Informed written consent will be gathered from each recruit prior to undertaking their radiographic examination (Appendix 6).

Any participant can withdraw from the study at any point prior to final data analysis, expected to start 1 month following the last recruit. Their data will be excluded from the study and study records destroyed. The radiographs obtained will be retained as part of their personal clinical record.

Study procedures

Imaging will be performed by specific study radiographers who will have received specialised training in undertaking pelvic radiography in the erect position. The training will be led by the study investigators, experienced radiographers with additional qualifications in image reporting.

Each patient will be radiographed in two positions, supine with a SID of 115 cm (current technique employed within the imaging department) and erect with a SID of 180cm (new comparison technique). Additionally the patient will have their height and weight measured to confirm the appropriate exposure parameters established in phase two.

The supine and erect radiographic examinations will be performed in a random order with the pre-printed data collection sheets indicating the order of the patient. This will be established using a random number generator. This procedure ensures that the patient preference cannot be related to the examination order.

Data collection and management

A data collection sheet will be used to record information about each study participant and the imaging parameters (Appendix 7). The data includes the anatomical measures (phase one and three) and exposure parameters (phase three only) and the patient will be asked their preference for the imaging technique (erect or supine). The data will be transcribed as soon as practicable into the Trust research management system EDGE with patient identifiable data being removed.

The additional erect pelvis projection will be stored on the MYT PACS system. Additionally anonymised copied will be stored to a study teaching file on PACS using their unique study identifier to allow blinded image review. The PI is a PACS administrator and will ensure this data is securely managed.

On completion of the recruitment data validation will take place to ensure there are no transcription errors and missing data. The final data set will be exported into Microsoft Excel for analysis. Further statistical analysis will take place using PCMXC and SPSS.

Data analysis

The phase three data will allow the comparison of the radiation dose (entrance surface dose (ESD) and effective dose (ED)) will be calculated using a commercially available computer software system which utilises Monte Carlo code dose simulation (PCMXC). Calculations will use the source-object distance, mAs and peak tube potential values (kV) for each exposure.

Descriptive analysis of the participant demographics and the image acquisition parameters will be undertaken, including patient preference and thematic analysis of any free text comments from the radiographer or patient. Comparison of examination length will be undertaken utilising the 'start time' and the time on the last image in that orientation, it is acknowledged this outcome will be influenced by the need for repeat exposures and technical difficulties in this small cohort.

Initial image quality will be assessed in relation to the diagnostic value of the radiograph and whether a repeat x-ray would have been warranted, this will allow comparison of repeat rates for the 2 examinations as well as the reasons. Further assessment of image quality will use a previously validated psychometric scale[31] to compare the noise at different anatomical regions. This will provide a comparison between the 2 projections, the images will be randomly allocated for analysis and reviewers will be blinded to the acquisition technique (erect or supine) for this analysis to reduce bias and maintain objectivity.

Ethical Consideration

The key ethical issue associated with this research is the requirement for an additional x-ray in phase three. Other options have been explored including using only an anthropomorphic phantom and randomization of patients to either examination. These strategies do not provide sufficient robustness to demonstrate changes on an individual basis and the phantoms have fixed bony and soft tissue anatomy and therefore do not allow comparison of changes related to posture.

REC and HRA approval will be sought to ensure the additional radiation dose is managed within an appropriate framework. This will include establishing protocols to limit radiation exposure through exclusion from the study if repeat x-rays are required due to quality reasons. A patient will only have one radiograph taken in the erect position, regardless of final image appearances. This will ensure that the maximum additional dose for a single patient is limited to one exposure whilst maintaining the integrity of their clinical examination. This will also provide information regarding the potential repeat rate for erect radiographs in a prospective future trial. The study team will then decide whether the patient is excluded from the study, included for limited analysis or fully included despite imaging appearances, on a case by case basis.

The number of radiographers able to obtain study images will be limited to provide quality assurance with the erect technique which is non-standard. These will undergo training and images will be assessed for quality throughout the study, providing opportunity for interventions if any variation from the protocol is identified.

Additional radiation dose reduction techniques will be adopted and these will be optimised during phase two of the study. Monitoring of patient radiation dose will be paramount, as with any imaging

study. A dose constraint will be established prior to ethical approval in line with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), if it is identified that certain patient groups are approaching this constraint a decision will be made to limit recruitment.

Patients will be informed of the study in advance, either with their radiology appointment letter or with clinic information depending on referral route. In addition posters will be distributed to GP surgeries and OP clinics to raise awareness. Patients will be provided information leaflets and the opportunity to discuss the study prior to the consent process.

Participants will be consented to the measures (and additional x-ray – phase 3 only) and will be able to withdraw their consent at any time during the radiology appointment without detriment to their care. Patients will be consented at time of their x-ray but will be given the chance to withdraw their data up to the start of data analysis, which is expected to be up to one month from end of recruitment. This information will be provided to patients. Permission to perform the additional measures (and x-ray) will be obtained in private prior to the examination within the radiology department. Confidentiality of participants will be maintained and the processes for data management will be compliant with the Data Protection Act (1998).

Source data, consent forms and patient screening questionnaires will be stored in a locked filing cabinet within a locked research office. Data transfer will be by encrypted Trust devices. Only the research team will have access to this data. All reports and dissemination of findings will only include anonymised data.

For all patients recruited their GP will be informed of their participation in the study regardless of the referral route (Appendix 8). Serious Adverse Event (SAE and Adverse Events (AE) will be documented in the study site file with a copy of the SAE sent to the head of research or R&D. All SAE/AE information will be emailed to MY.Research@midyorks.nhs.uk and the lead member of staff at the study site at the start of each calendar month as per local processes.

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Appendix 1. Phase 1: Patient information sheet

A pilot study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic quality (SEPRAIDD)

Why we are inviting you to take part in this research?

You have been referred for an x-ray (radiograph) of your hip or pelvis and we want to invite you take part in a research study looking at the best way to take these x-rays. Before you make your decision it is important for you to understand why the research is being done and what it will involve.

Please take time to read the information carefully. You may want to talk to others about the study before taking part. Please ask us if there anything unclear or if you would like more information. A telephone number has also been provided overleaf.

What is the purpose of the study?

X-Ray images are the most common tool for investigating diseases of the hip joint. Being able to compare these images over time is important. When patients have pelvic x-rays taken they are asked to lie on an x-ray table. We want to know whether it would be beneficial to take the x-ray standing up.

For some patients this may be more comfortable or may show different abnormalities. In the first part of this research we want to look at how the body changes between lying and standing.

What would taking part involve?

You are being asked to consent to a member of the radiographic team taking measurements of your height and weight before your x-ray examination, followed by body measurements taken at three points when you are standing and lying down. You will still only have the x-ray taken in the standard lying down position.

What are the possible benefits of taking part?

There will be no direct benefit to you in taking part.

These measurements will enable us to work out the best technique to take x-rays in the standing position to ensure the highest quality with the lowest possible radiation dose. A future part of the research will be to take the x-rays in both lying and standing positions.

What are the potential disadvantages and risks of taking part?

The disadvantage is the time taken to complete the consent process, and to undertake the measurements required for the study. This may take up to fifteen minutes.

Do I have to take part in the study?

No, it is up to you whether you choose to take part in the study.

When you attend for your appointment you may be asked whether you want to take part. Participation in the research is voluntary and if you wish to participate in this study, you will be provided with a consent form to sign. Even if you agree to take part on the day of your x-ray appointment you can change your mind.

Data Sharing

Your data will be made anonymous as soon as possible and will only be accessed by staff directly involved within the study, including the Mid Yorkshire Hospitals NHS Trust and the Universities of Bradford and Salford.

All study data will be held in secure locations and will be destroyed three years after the end of the study.

Study Results

A newsletter style copy of the study outcomes will be freely available to any participant who wishes to view it. In order to receive this, please leave an electronic contact on your consent form.

The findings of this study will be reported nationally and locally in the hospital newsletter.

The data and results stated in these publications will be anonymous.

Supporting Information

If you change your mind and wish to withdraw from the study please contact us on the telephone number below, up to the start of data analysis (1 month from end of recruitment). This will not affect your medical care in any way.

How to contact us:

If you have questions about this research study or wish to withdraw your data from the study, please contact us on :

01924 542297

or email

radiology.research@midyorks.nhs.uk

If you have general questions about taking part in research, please contact :

01924 543771

Appendix 2. Phase 1: Consent form

Study ID number:

CONSENT FORM

A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet (version....., dated……) for the above research study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and am satisfied with the answers to my questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw my data up to data analysis without giving any reason and without my medical care or legal rights being affected. ☐
3. I give permission for height, weight and body circumference measurements to be undertaken and stored. ☐
4. I understand that the radiographic images taken for this study will be retained and will be used to support future research and sub-analysis. ☐
5. I agree to my General Practitioner being informed of my participation in the study ☐
6. I understand that data collected during the study, may be looked at by individuals from organisations involved in developing and running this research, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, but understand that my confidentiality will be maintained. ☐
7. I agree to take part in the above study. ☐
8. I would like to receive a copy of the summary of findings for this study or be sent the details of a link to the location of the findings. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Witness (If applicable)	Date	Signature

Appendix 3. Phase 1: Data collection instructions

A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Preparation

Patient will have been greeted by a GCP trained radiographer who will introduce themselves and explain the study, prior to obtaining consent. If consent is gained then the patient will complete paperwork and be asked to change in to a gown as required for their examination.

If the examining radiographer is different to the one obtaining consent repeat ID checks should be undertaken following introduction of self. Confirmation of participant agreement to proceed should be sought verbally.

Study procedure

Height and Weight should be undertaken on the study calibrated weigh scale, in cm and kg.

A disposable 150cm tape measure should be used to measure body circumference at the levels of the lower costal margin, the iliac crests and the greater trochanter. Source-patient distance will be measured using the built in tape measure on the x-ray tube within the room.

1. The patient should be positioned AP against the erect bucky. The tape is passed around their body, the appropriate landmark palpated ensuring that the tape is parallel to the floor. The measurement should be taken whilst the patient is in arrested expiration and recorded on the data collection sheet. This is repeated for all three anatomical levels.
2. The patient should be asked to remain in the same standing position whilst the tube head is positioned at 115cm SID. The light beam is used to centre the tube at the level of the iliac crests. Measurements are taken, using the built in tape measure at the tube head, in the midline at the level of the lower costal margin, iliac crests and greater trochanters (to correlate with tape measure circumference readings). Arrested expiration should again be utilised.
3. The patient is then asked to lie on the bucky table which is then set at its normal height. Tape measurements of body circumference are again made at the same three levels, this time ensuring that the tape measure remains perpendicular to the table top. The tube head is placed at 115cm SID, above the patient, and centred in the midline at the level of the lower costal margin. The built in tape measure at the tube head should be used to take a measurement at the level of the lower costal margin. The floating table top is then used to repeat these measurements centred over the iliac crests and greater trochanters.
4. The patient should then be thanked for their cooperation and their radiographic examination is undertaken.
5. The tape measure should be disposed of following completion of the examination.

Appendix 4: Phase 1: Data collection sheet

A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Study ID Number: _____

Patient Hospital Number: _____

Height: _____m__ **Weight:** _____kg____

Age: _____ **Gender:** M / F

Erect Position (Source-Centring): _____ (Lower costal margin)

_____ (Iliac crests)

_____ (Greater trochanter)

Body circumference (Erect): _____ (Lower costal margin)

_____ (Iliac crests)

_____ (Greater trochanter)

Supine Position (Source-Centring): _____ (Lower costal margin)

_____ (Iliac crests)

_____ (Greater trochanter)

Body circumference (Supine): _____ (Lower costal margin)

_____ (Iliac crests)

_____ (Greater trochanter)

Appendix 5. Phase 3: Patient information sheet

A pilot study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic quality (SEPRAIDD)

Why we are inviting you to take part in this research?

You have been referred for an x-ray (radiograph) of your hip or pelvis and we want to invite you take part in a research study looking at the best way to take these x-rays. Before you make your decision it is important for you to understand why the research is being done and what it will involve.

Please take time to read the information carefully. You may want to talk to others about the study before taking part. Please ask us if there anything unclear or if you would like more information. A telephone number has also been provided overleaf.

What is the purpose of the study?

X-Ray images are the most common tool for investigating diseases of the hip joint. Being able to compare these images over time is important. When patients have pelvic x-rays taken they are asked to lie on an x-ray table. We want to know whether it would be beneficial to take the x-ray standing up.

For some patients this may be more comfortable or may show different abnormalities.

We want to look at patient perspectives of the 2 techniques as well as the appearances of the x-ray and what differences they show between lying and standing. We need to compare the radiation dose for techniques to ensure patients receive the lowest dose possible.

What would taking part involve?

You are being asked to consent to a member of the radiographic team taking an extra pelvis x-ray in addition to that which would normally be obtained. This x-ray will be obtained with you standing upright rather than lying on the examination table.

We need to take measurements of your height and weight before the x-ray is performed to ensure the examination is of optimal standard. After the x-ray you will also be asked your preference for position (lying or standing). By participating in this study you are consenting to these x-rays being retained for a period of 3 years to support future research and analysis in this area.

What are the possible benefits of taking part?

There will be no direct benefit to you in taking part.

These x-rays will enable us to compare the two different positions and may help change future practice so that these examinations can be performed to provide the best detail and patient satisfaction.

What are the potential disadvantages and risks of taking part?

The main disadvantages are the increased time for the examination and the radiation dose for the additional x-ray. The time taken to complete the consent process and have the second x-ray performed is likely to require an additional ten minutes of your time. The lowest possible dose will be

utilised and the equipment has been set up to ensure consistency. The additional radiation dose you receive will be less than the normal amount of background radiation you would receive in a 6 week period.

Do I have to take part in the study?

No, it is up to you whether you choose to take part in the study.

When you attend for your appointment you may be asked whether you want to take part. Participation in the research is voluntary and if you wish to participate in this study, you will be provided with a consent form to sign. Even if you agree to take part on the day of your x-ray appointment you can change your mind.

Data Sharing

Your data will be made anonymous as soon as possible and will only be accessed by staff directly involved within the study, including the Mid Yorkshire Hospitals NHS Trust and the Universities of Bradford and Salford.

All study data will be held in secure locations and will be destroyed three years after the end of the study. The additional x-ray taken will be held with your other x-rays to be permanently available for clinicians looking after your care.

Study Results

A newsletter style copy of the study outcomes will be freely available to any participant who wishes to view it. In order to receive this, please leave an electronic contact on your consent form.

The findings of this study will be reported nationally and locally in the hospital newsletter.

The data and results stated in these publications will be anonymous.

Supporting Information

If you change your mind and wish to withdraw from the study please contact us on the telephone number below, up to the start of data analysis (1 month from end of recruitment). This will not affect your medical care in any way.

How to contact us:

If you have questions about this research study or wish to withdraw your data from the study, please contact us on :

01924 542297

or email

radiology.research@midyorks.nhs.uk

If you have general questions about taking part in research, please contact :

01924 543771

Appendix 6. Phase 3: Consent form

Study ID number:

CONSENT FORM

A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet (version....., dated……) for the above research study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and am satisfied with the answers to my questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw my data up to data analysis without giving any reason and without my medical care or legal rights being affected. ☐
3. I give permission for a second radiograph of my hips to be undertaken in an erect position. ☐
4. I understand that the radiographic images taken for this study will be retained and will be used to support future research and sub-analysis. ☐
5. I agree to my General Practitioner being informed of my participation in the study ☐
6. I understand that data collected during the study, may be looked at by individuals from organisations involved in developing and running this research, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records, but understand that my confidentiality will be maintained. ☐
7. I agree to take part in the above study. ☐
8. I would like to receive a copy of the summary of findings for this study or be sent the details of a link to the location of the findings. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Witness (If applicable)	Date	Signature

Appendix 7. Phase 3: Data collection sheet

A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)

Study ID Number: _____ **Imaging order**

Patient Hospital Number: _____

Height: _____m__ **Weight**: _____kg____

Age: _____ **Gender:** M / F

Supine radiograph
Start time:

kV _____

mAs _____

DAP _____

EI _____
Image time:

Repeat Yes/No

kV _____

mAs _____

DAP _____

EI _____

Erect radiograph
Start time:

kV _____

mAs _____

DAP _____

EI _____
Image time:

Comments:

Patient preference

Supine / Erect

Radiographer code:

Appendix 8. GP letter

The Mid Yorkshire Hospitals NHS
NHS Trust

Radiology Research
Rowan House
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG
Tel: 01924 542034
Email: radiology.research@midyorks.nhs.uk

Date:

Doctor name and address:

Dear Doctor,

Re:

[Patient name and address] [Patient date of birth]

The above patient has kindly agreed to take part in a research project titled: ***A study to compare supine and erect pelvis radiographs – assessment of impact on radiation dose and diagnostic markers (SEPRAIDD)***. This is a study assessing the feasibility of undertaking pelvic radiographs in the erect position and its impact on radiation dose and diagnostic outcomes.

The purpose of the study is to: recruit outpatients attending the radiology department for pelvis radiography as part of their standard care. Patients will be asked to consent to a second radiograph being performed in addition to the normal radiograph that is undertaken. This second radiograph will be performed with the patient in an erect position.

A copy of the participant information sheet is enclosed for your information. Should you have any questions regarding this study, please do not hesitate to contact me, the Chief Investigator, by email at radiology.research@midyorks.nhs.uk, or phone 01924 542034.

Yours sincerely,

Mr Kevin Flintham
Advanced Radiographer Practitioner
Principal Investigator (SEPRAIDD)

Version No: 1 **Date:** 19/07/2017

Appendix 9. Gantt Chart

	2017					2018				
Month	August	September	October	November	December	January	February	March	April	May
Project set up	1,2	3	4,5		6					
Steering group meetings										
Staff training										
Phase 1 recruitment										
Phase 2 experiment										
Phase 3 recruitment							7			
Data analysis										
Report production								8	9	
Dissemination									10	

	Deliverables	
	1. MYT sponsor R&D approval 2. IRAS submission 3. Study staff identification 4. HRA approval 5. MYT confirmation of capacity and capability	6. Phase 3 acquisition procedures finalised 7. Recruitment complete 8. Interim report 9. Final report 10. Commence dissemination

Version: 2 **Date:** 09/08/2017

Appendix 10. Study Flow Chart