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Testing a different centring point for pelvic x-rays

Submission date 09/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/07/2021	**Overall study status** Completed	
Last Edited 13/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Radiographic (x-ray) projections should be standardised for consistent and accurate interpretation and measurements, but textbooks and clinical practice describe various methods. This variation can lead to problems with measurements that determine patient outcomes, and this is particularly evident within pelvic radiography. This has implications for orthopaedic surgeons who need accurate measurements to plan hip replacements and assess the joints. In some instances, radiographers 'centre low' to demonstrate the hips, whereas others include iliac crests as a true 'pelvis'.
The aim of this study is to provide evidence for a different centring point that has been developed from a previous image review study and determine its reliability and acceptability to radiographers. Providing evidence for the optimum position is the first step to ensure radiography is evidence-based and allows future development of an evidence base for other body parts. In addition, it provides a platform from which to consider changes to technique, such as the increasing requirement for weight-bearing images.

Who can participate?
Patients aged over 18 years referred for a pelvic radiograph from outpatient (OP) clinics and general practitioners (GPs)

What does the study involve?
This study will use two clinical radiography sites based in two NHS hospitals to compare the use of the different standardised techniques for pelvic radiography. An audit will examine the quality of pelvic radiographs that were undertaken at both sites between July to October 2019 (to account for practice variation in 2020 due to COVID-19). Any issues identified with quality will be addressed through a training package given to both sites and provided by the researchers.
One site will continue with current practice (the control site) and the other site will use the different technique which is based on the audit (the intervention site). Radiographers at the intervention site will undergo additional training to ensure adherence to the different procedure. The prospective radiographs from both sites will be compared. Radiographers will be asked to document any comments in relation to the examination.

What are the possible benefits and risks of participating?
There are no expected risks from taking part in the study as the x-ray is being delivered as part of routine care. Participants will not undergo any additional imaging procedures to normal. These procedures use ionising radiation to form images of the body and provide clinical information. Ionising radiation can cause cell damage that may after many years or decades turn cancerous. The chances of this happening are the same whether patients take part in this study or not. There are no advantages personally in taking part in the study but the information from the study will help improve the care of patients with similar problems in the future and provide valuable information on the use of NHS resources.

Where is the study run from?
1. The Mid Yorkshire Hospitals NHS Trust (UK)
2. Warrington and Halton Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to October 2022

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

Who is the main contact?
Dr Fiona Mellor
F.E.Mellor@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Fiona Mellor

ORCID ID
https://orcid.org/0000-0002-5872-3469

Contact details
Chief Investigator
School of Radiology
AECC University College
13-15 Parkwood Road
Bournemouth
United Kingdom
NH5 2DF
+44 (0)7818 552107
F.E.Mellor@exeter.ac.uk

Type(s)
Scientific

Contact name
Prof Bev Snaith

ORCID ID
https://orcid.org/0000-0002-6296-0889

Contact details
University of Bradford and Mid Yorkshire Hospitals NHS Trust
Unit 10, Clarke Hall Farm
Aberford Road
Wakefield
United Kingdom
WF1 4EE
+44 (0)1924 542034
Beverly.snaith@nhs.net

Type(s)
Scientific

Contact name
Dr Andrew England

ORCID ID
https://orcid.org/0000-0001-6333-7776

Contact details
UGF 14 ASSERT
Brookfield Health Sciences
University College Cork
Cork
Ireland
T12 AK54
+353 (0)21 420 5656
aengland@ucc.ie

Type(s)
Scientific

Contact name
Miss Martine Harris

ORCID ID
https://orcid.org/0000-0003-1924-3718

Contact details
Mid Yorkshire Hospitals NHS Trust
Unit 10
Clarke Hall Farm
Aberford Road
Wakefield
United Kingdom

WF1 4EE
+44 (0)1924 542297
Martine.harris@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294098

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49054, IRAS 294098

Study information

Scientific Title
STandardisation Of suPine Pelvic rAdioGraph tEchnique (STOPPAGE). Validating a different centring point for pelvic radiographs in a supine position

Acronym
STOPPAGE

Study objectives
The different centring point will reduce the variability in pelvic radiograph measurements and be more acceptable to radiographers than the current standard of positioning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2021, Berkshire REC (South Central Region) (Bristol REC Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8224, +44 (0)207 104 8270; berkshire.rec@hra.nhs.uk), REC ref: 21/SC/0130

Study design
Non-randomized; Both; Design type: Process of Care, Imaging, Cross-sectional

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pelvic radiograph

Interventions

This study will test the different centring point for reliability and acceptability. Two NHS clinical sites in England will be used with one undertaking pelvis radiography according to the different technique (intervention site) and the other continuing with standard practice (active control site).

Retrospective audit:
Pelvic radiographs from both sites obtained for the same time period (June to October 2019, to reflect practice not affected by COVID) to identify any recurrent issues with quality (rotation, included anatomy, and image quality). Differences and similarities between the two cohorts will be assessed.

Prospective data collection:
All radiographers at the interventional site will undertake training on the different centring point, consisting of a video presentation and online Q&A session to embed the different technique. The training will be based on the literature, retrospective audit, and the findings of a recent unpublished evaluation that demonstrated high variability of centring points within pelvic radiographs and supported the proposal for a different centring point. The control group will also have a refresher update on pelvic positioning based on the retrospective audit. They will then continue with their usual practice.
During the data collection period radiographers at both sites will complete the CRF to determine their ease of locating the bony landmarks and be asked to rate their resultant radiograph. They will also be asked to provide any free text comments regarding the positioning technique they used. (Acceptability of the positioning technique for patients will not be assessed as all their data will be anonymised at source and unless they have experience of previous pelvic imaging their views may not be valid).

Sampling strategy
A convenience sample of patients requiring pelvic radiography at both sites between July and October 2021 (4-month period) who fit the inclusion-exclusion criteria. At one site it is estimated that 1260 patients will be eligible. At the other site the estimation is between 480 to 600 patients. This is based on the same time period in the previous year. This time frame may be fluid based on COVID-19 and diagnostic recovery plans.

Sample size
Based on unpublished pilot data, we would aim to reduce centring point variation with an effect size of 75%. This would require a total sample size, between the two study sites, of 314 (significance level 5%, power 80%) and would be achievable given the workload between the sites. Recruitment would be on a 1:1 basis.

Recruitment process
Patients presenting for pelvic radiography who fit the inclusion-exclusion criteria will be sent a participant information sheet (PIS) with their appointment or given one in clinic or on arrival in radiology. Posters explaining the research will also be placed in each Department's waiting area.

A core group of study delivery radiographers, who have received research awareness training approved by the HRA and CRN, will be responsible for obtaining informed written consent at both sites. Patients who agree to take part will sign a consent form agreeing to the use of their anonymised data. The number of patients approached versus the number recruited will be recorded in a screening log.

Data collection method
Retrospective audit data from both sites will consist of measurements (rotation, included anatomy, and image quality) from anonymised pelvic radiographs from OP and GP clinics. This will be reviewed at a site level and compared across sites by the researchers.
Prospective data from both sites will include patient demographics (age, gender, height, and weight) and sagittal diameter at the centring point. This will be recorded for each patient in the X-ray room to maintain dignity. The justification for imaging and the resultant radiograph, along with any repeats, will be collected by the research group.

Consented patients will undergo pelvic radiography based on the different technique or usual care, dependent upon which site they presented. The radiographer will record this, alongside the patient demographics detailed above and justification for imaging on a case report form (CRF). The records will be anonymised and stored in a locked filing cabinet prior to analysis. The records sheet will be retained by the research team and anonymised data will be uploaded to the EDGE research management software to enable recruitment information to be collated by the NIHR portfolio and local CRN. Export of the data attributes from EDGE will be undertaken and the completely anonymised database shared with the research team for analysis. Anonymised images will be collected in DICOM format enabling analysis to be undertaken remotely. The radiation dose data will also be recorded.

Radiographers will be asked to complete the CRF with their comments on the ease of locating the bony landmarks and the quality of the resultant radiograph.

Data analysis
Retrospective audit data from both sites will be evaluated to determine consistency in axial, sagittal and coronal rotation; image quality, and included anatomy.
Prospective data from both sites will be analysed with descriptive and inferential statistics (if the data is normally distributed). Data will be stratified according to Body Mass Index (BMI) in the following categories:
1. Underweight/normal (BMI <25 kg/m^2)
2. Overweight (BMI 26-30 kg/m^2)
3. Obese/morbidly obese (BMI >30 kg/m^2)
The primary analysis will determine the reliability of the centring point in the different technique versus usual care for sagittal, axial and coronal rotation, image quality, and included anatomy.

Secondary data analysis will compare prospective data within and between both sites to determine if the training and implementation of the different technique has any effect on the following:
1. Obturator width left and right
2. Axial pelvic rotation (degrees)
3. Inter-acetabular line
4. Pelvic outlet diameter
5. Femoral head diameter left and right
6. Inter-trochanter width
7. Radiation dose
8. Number of repeat radiographs
9. Image quality
10. Included anatomy
For radiation dose data and the number of repeats and the median and 75th percentile will be compared.
Prospective data will be compared to data from the retrospective audit in terms of rotation,

image quality and missing anatomy to measure the impact of the audit on the prospective results.
The anonymised staff comments on the individual patient CRFs across both study arms will be descriptively analysed and a thematic analysis undertaken of any free text comments

Intervention Type
Procedure/Surgery

Primary outcome(s)
The reliability of the evidence-based centring point in the different technique versus usual care for sagittal, axial and coronal rotation, image quality and included anatomy, assessed by image review of radiographs at a single timepoint

Key secondary outcome(s))
Assessed at a single timepoint:
1. Differences in radiological measurements between techniques, assessed using image review of radiographs for sagittal, axial and coronal rotation
2. The radiation dose of the techniques assessed using dose area product (DAP) - median and 75th percentiles
3. Differences in the number of repeat radiographs between techniques, measured using the number of repeat radiographs performed - median and 75th percentiles
4. Image quality between techniques assessed by the subjective opinion of the operator and the Exposure Index
5. The included anatomy between techniques, assessed by image review of radiographs for missing anatomy
6. Qualitative opinions of the staff performing the radiographs assessed using the Likert scale of ease/difficulty in palpating the required anatomy for the technique and thematic analysis of CRF free text comments

Completion date
31/10/2022

Eligibility

Key inclusion criteria
All patients referred for a pelvic radiograph from outpatient (OP) clinics and general practitioners (GPs)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
289

Key exclusion criteria
1. Patients referred for one or both hip radiographs (XHIPB) as the resultant images do not include the same anatomy as a true pelvis radiograph
2. Anyone with a hip prosthesis as the anatomical measures will not be valid
3. Immobile patients who may need additional adjustments to techniques
4. Patients <18 years old or pregnant
5. Those unable to read the participant information leaflet (PIS) or unable to provide informed written consent due to a lack of capacity (Mental Capacity Act)
6. Patients who are prisoners or in police custody to minimise examination times, reduce anxiety and overall risk

Date of first enrolment
01/08/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pinderfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Warrington Hospital
Warrington and Halton Teaching Hospitals NHS Foundation Trust
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Sponsor information

Organisation
Anglo-European College of Chiropractic

ROR
https://ror.org/03rd8mf35

Funder(s)

Funder type
University/education

Funder Name
Society and College of Radiographers (SCoR); Grant Codes: 194

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 v1.1	26/04/2021	23/07/2021	No	Yes
Participant information sheet	version 1.2	18/12/2021	05/01/2022	No	Yes
Protocol file	version v1	23/03/2021	23/07/2021	No	No
Protocol file	version 1.2	18/12/2021	05/01/2022	No	No