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Exploring the use of extremity cone beam computed tomography (CBCT) technology in the emergency department (ED) for patients with suspected scaphoid fracture

Submission date
02/03/2020

Recruitment status
No longer recruiting

Registration date
20/04/2020

Overall study status
Completed

Last Edited
30/11/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The scaphoid is a small bone in the wrist commonly broken during falls. Unfortunately, many fractures are not visible on initial x-rays and there can be a delay before the fracture is identified during which the patient must be immobilised and repeatedly visit hospital. X-rays have poor predictive value for scaphoid fractures and other imaging tests such as MRI and CT can be used. However, practice varies across the UK and serial x-rays continue to be the standard diagnostic protocol for imaging. The Mid Yorkshire Hospitals NHS Trust has recently revised the scaphoid fracture pathway to incorporate new extremity Cone Beam Computed Tomography (CBCT) technology. This study aims to find out if the implementation of extremity CBCT in this context enables earlier diagnosis and increased efficiency for both patients and the hospital services.

Who can participate?
All patients over 18 years of age who present at the Emergency Department with a wrist injury and have a suspected scaphoid fracture can participate. Participants must have a positive clinical examination, no other significant injuries, be able to provide informed consent and adhere to questionnaire completion.

What does the study involve?
Participants are consenting to the recording of routinely collected information and their emergency department visit and imaging investigations for the scaphoid injury collected from standard hospital systems. They are asked to complete a questionnaire at baseline about the pain and function before and after the injury. If the initial four-view scaphoid x-ray is normal, they will have an extremity cone beam CT scan of the wrist for further evaluation. If this scan is also normal, a member of the research team will contact them after two weeks (in line with standard follow up) and again at 6 weeks to see if they have recovered as expected. During these telephone calls, many of the same questions asked at baseline will be repeated.

What are the possible benefits and risks of participating?
There are no expected risks from taking part in the study as the x-ray and CT wrist scan are delivered as part of routine care. If taking part in the study, participants you will not undergo any additional imaging procedures to normal. These procedures use ionising radiation to form images of the body and provide clinicians with clinical information. Ionising radiation can cause cell damage that may, after many years or decades turn cancerous. The chances of this happening to are the same whether participating in this study or not.
Follow up telephone calls will be kept as short as possible and we will work with participants to perform them at a time that is convenient. There are no advantages to taking part in the study but being part of the research will provide reassurance in ongoing management of the injury and will allow participants to alert the clinical team of any on-going symptoms. If there are ongoing problems, we will arrange review in a hospital clinic. The information we get from the study will help us improve care of patients with similar injuries in the future and provide valuable information on the use of NHS resources.

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

When is the study starting and how long is it expected to run for?
March 2020 to August 2020

Who is funding the study?
Carestream Health (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
274018

Protocol serial number
1.2 24/02/2020

Study information

Scientific Title
Improving the Scaphoid Pathway with Extremity CT in the ED: The InSPECTED Study

Acronym
InSPECTED

Study objectives
Early access to cross-sectional imaging through the utilisation of Cone Beam Computed Tomography (CBCT) could streamline the imaging and management pathway for patients with suspected scaphoid fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2020, The Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8388; leicestercentral.rec@hra.nhs.uk), ref: 20/EM/0012

Study design

Single-centre observational

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Suspected scaphoid fracture

Interventions
All participants will be identified as part of their Emergency Department (ED) attendance for wrist injury, and formally consented for participation in the study. Following clinical assessment by an ED Doctor or Emergency Nurse Practitioner (ENP) and completion of a scaphoid screening tool in standard use at the host site, participants with a suspected scaphoid fracture will be referred for four-view scaphoid x-ray. Where this x-ray is normal further diagnostic evaluation by CBCT scan will be performed. This is standard clinical practice at the host site. Research participants with a normal CBCT scan will be followed up at 2-weeks and 6-weeks with telephone interviews, similar to current virtual clinics. Questions relate to their wrist pain and function as well as validated quality of life assessment. At these data collection time points, patients who meet specific criteria regarding ongoing symptoms (increased PROMs score or analgesia use) will be reviewed in a (physical) specialist musculoskeletal ED clinic with appropriate further imaging investigations or alternatively may be referred for physiotherapy if the symptoms persist. Those who consent to participation in the study are also agreeing to the collection of routine hospital data accumulated during their ED attendances related to the injury.
This prospective cohort will be compared to a retrospective sample of patients utilising the same criteria and timeframe during the preceding year.

Intervention Type
Other

Primary outcome(s)
Number of hospital attendances related to the suspected scaphoid fracture measured at the end of the study using patient records.

Key secondary outcome(s))
Measured using patient records unless otherwise indicated:
1. Number of patients presenting at ED with suspected scaphoid fracture* at baseline
2. Number of patients diagnosed with scaphoid fracture on imaging (prevalence)* at baseline
3. Number and type of imaging investigations (x-rays, CBCT, CT and MRI scans)* at baseline
4. Pathway timings* at baseline
5. Unplanned returns to the ED* at 2 weeks and 6 weeks
6. Planned recalls to the ED* at 2 weeks and 6 weeks
7. ED discharge and referral rates* at baseline
8. CBCT failure rates/delays (patient, technical, staff) at baseline
9. Patient demographics* at baseline
10. Injury demographics including time of presentation, clinical symptoms, injury mechanism and fracture type (if appropriate)* at baseline
11. Patient reported outcome measures (from CRF) at 2 weeks and 6 weeks
11.1. Patient-Rated Wrist Evaluation (PRWE)

11.2. Health Economics/Quality of Life outcomes (EQ-5D-5L)
12. Healthcare resource use at 2 weeks and 6 weeks
13. Radiation dose associated with scaphoid fracture diagnosis / exclusion* at baseline
14. Recruitment rate (assumed consent)
15. Patient baseline CRF (EQ5D-5L and PRWE) completion rates at baseline
The data marked with * will also be collected for the retrospective cohort

Completion date
28/08/2020

Eligibility

Key inclusion criteria
1. Present at any of the EDs across the Trust with a mechanism of injury consistent with scaphoid trauma and a positive clinical examination
2. Over the age of 18 and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Do not present via the ED
2. Have an additional injury, which may affect the primary outcome measure
3. Evidence that the patient would be unable to adhere to study or procedures or complete questionnaires, for example has cognitive impairment

Date of first enrolment
04/03/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Pinderfields Hospital
The Mid Yorkshire NHS Trust
Aberford Road
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Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Industry

Funder Name
Carestream Health

Alternative Name(s)
Carestream Health Inc., Carestream Health Incorporated

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?
Results article		18/11/2021	30/11/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version v1.2	24/02/2020	20/04/2020	No	No