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Streamlining cross-sectional imaging pathways (SCIPs)

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
04/04/2017

Overall study status
Completed

Last Edited
08/04/2019

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Computerised Tomography (CT) is a radiology test which takes cross-sectional images of the body using radiation (x-rays) and is vital for diagnosing (or excluding) cancer. To improve the visibility of internal organs and structures on these scans, an x-ray dye is injected into the bloodstream. This x-ray dye is commonly referred to as contrast media. In patients with reduced kidney function, the use of contrast media can cause complications. Guidelines published by the Royal College of Radiologists (RCR) recommend a blood test to measure kidney function should be available from the preceding three months for all patients referred for CT scans including contrast. There are a variety of pathways to ensure that a blood test is performed before the scan, some of which may delay imaging. The blood test allows patients with reduced kidney function to be identified, as there is a risk of Contrast Induced Acute Kidney Injury (CI-AKI). As the waiting time for imaging tests are reduced, it is important to identify how services can be streamlined. A national survey undertaken by the research team has demonstrated diversity in the current service delivery pathways for obtaining kidney function prior to cross-sectional imaging across the UK. A small number of sites offer point of care testing (PoCT) for kidney function in patients who have not had a recent blood test. However, the potential impact of their application is unknown. The aim of this study is to evaluate whether PoCT devices for determining kidney function levels can be used to streamline the patient pathway.

Who can participate?
Adult patients who are attending an appointment for a contrast-enhanced CT scan

What does the study involve?
When participants attend for their CT appointment they have an additional blood sample taken. The sample is then analysed using the PoCT device and is also sent to the lab so it can undergo standard testing to assess participant's kidney function. Participants are asked to return for another study visit 2-3 days later for a follow up blood test which is analysed the same way.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
1. Pinderfields Hospital (UK)
2. Dewsbury District Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to May 2017

Who is funding the study?
NHS England (UK)

Who is the main contact?
1. Miss Martine Harris (public)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33308

Study information

Scientific Title
Streamlining cross-sectional imaging pathways (SCIPs): A feasibility and economic modelling study of point of care creatinine testing in radiology

Acronym
SCIPs

Study objectives
The aim of this study is to assess the feasibility of using a point of care blood test (PoCT) performed in radiology rather than the standard laboratory test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield Research Ethics Committee, 09/01/2017, ref: 16/YH/0520

Study design
Non-randomised; Both; Design type: Screening, Diagnosis, Device, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Renal failure

Interventions
The intervention is a PoC creatinine test and a standard laboratory renal function blood test performed at the initial visit (CT scan appointment), this will take 5 minutes. This whole blood sample is processed on the point of care device according to manufacturer's recommendations. The standard care blood sample is analysed in the laboratory on a Roche Cobas 8000 series, using an enzymatic creatinine method, according to standard operating procedures.

Participants will be asked to return at 2-3 days post-contrast administration for a follow up blood test to be analysed on both the PoC device and in the laboratory.

Intervention Type
Device

Primary outcome measure
Renal function concordance measured as the difference between the serum creatinine value from PoCT and laboratory analysis at initial visit.

Secondary outcome measures
1. Recruitment rate recorded as the number of eligible participants who consented to participate in the study at initial visit
2. Attrition rate recorded as the number of participants that return for follow up blood test at 2-3 days post-contrast administration
3. Failure rate recorded as the number of test analyses which do not produce a result from PoC and laboratory tests at initial and follow up visits
4. Screening questionnaire effectiveness measured as the number of patients with no risk factors who have a reduced renal function identified (eGFR <40) at initial visit
5. Renal function recorded as the concordance between serum creatinine and eGFR from the pre-scan result obtained within 3 months of scan and the renal function at initial visit
6. Rate of contrast-induced acute kidney injury (CI-AKI) recorded as the number of participants who have a ≥25% rise in serum creatinine on follow up blood test 2-3 days post-contrast administration

Overall study start date
01/10/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Patients attending for contrast-enhanced CT scan
2. Age over 18

3. Non-pregnant patients
4. Able to consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. Patients undergoing a non-contrast CT scan or other radiology test
2. Patients under 18 years
3. Pregnant patients
4. Those unable to provide written consent

Date of first enrolment
15/02/2017

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Dewsbury District Hospital
Halifax Road

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United Kingdom
WF13 4HS

Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer reviewed journal
2. Presentation at UK Radiological Congress June 2017

Intention to publish date
01/10/2018

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019		Yes	No
HRA research summary			26/07/2023	No	No