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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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2. Dr Bev Snaith (scientific)
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# Contact information

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Public

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# Additional identifiers

### Protocol serial number
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

### Primary study design
Interventional

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

### Study type(s)
Treatment

### 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(s)
Renal function concordance measured as the difference between the serum creatinine value from PoCT and laboratory analysis at initial visit.

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### 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
United Kingdom

England

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

### Study participating centre
**Dewsbury District Hospital**
Halifax Road
Dewsbury
United Kingdom
WF13 4HS

## Sponsor information

### Organisation
Mid Yorkshire Hospitals NHS Trust

### ROR
https://ror.org/05g23q746

## Funder(s)

**Funder type**
Government

**Funder Name**
NHS England

# Results and Publications

## 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 |