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Method comparison and bias estimation of point

Submission date	Recruitment status	[_] Prospectively registered
14/08/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/08/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/07/2018	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
When patients need an x-ray they first need to have a blood test to check that their kidney function (estimated Glomerular Filtration rate [eGFR]) is normal. The blood test identifies patients with reduced kidney function as they are at risk of kidney injury as a result of the injection of x-ray dye. The aim of this study is to test whether a point of care test (POCT) is as accurate as a standard test to see whether it can be used to improve patient care.

Who can participate?
Patients aged over 18 who are already having a blood test (U&Es)

What does the study involve?
Participants undergo a standard blood test and extra blood tests using POCT devices using both venous (vein) and finger prick blood. The results of the blood tests are compared.

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

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

When is the study starting and how long is it expected to run for?
February 2016 to November 2016

Who is funding the study?
Yorkshire & Humber Academic Health Science Network (UK)

Who is the main contact?
Miss Martine Harris

Contact information

Type(s)
Scientific

Contact name
Miss Martine Harris

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31955

Study information

Scientific Title
Method comparison and bias estimation of point of care creatinine tests against standard of care laboratory testing by enzymatic method

Acronym
BEPoCC

Study objectives
The aim of this study to test whether a point of care test (POCT) for bloods is as accurate as a standard pathology test to enable it to be considered for use in radiology to improve patient care pathways. This will enable the trialists to develop a trial to evaluate the impact of POCT on a Radiology service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland REC2, 13/06/2016, IRAS: 202240, REC ref: 16/SS/0077

Study design
Non-randomised; interventional and observational. Design type: Validation of outcome measures

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Blood/ Other diseases of blood and blood-forming organs

Interventions
Additional blood tests are performed utilising POCT devices on outpatients routinely referred to phlebotomy for blood (U&E) testing as part of their standard pathway. Patients will be identified as attending for U&E's in the phlebotomy department and those attending for other blood tests will be excluded. Patients identified will be recruited and consented for their agreement to have both a standard pathology blood test and a POCT (using both venous and capillary finger prick) blood. Accuracy using method comparison and bias estimation will be carried out on the patient samples in accordance with established laboratory standards.To ensure patients with a range of blood results are identified a modified Choyke screening questionnaire will be used to identify those with potentially reduced kidney function who would be the group most at risk in any future radiology based studies.

Intervention Type
Device

Primary outcome measure
Renal function concordance measured as the difference between Estimated Glomerular Filtration Rate (eGFR) measurements calculated from serum creatinine measurements recorded by the standard pathology test and each point of care device (not POCT vs POCT); Timepoint(s): Day 1 only

Secondary outcome measures
1. Failure rates, recorded as the number of test analyses which do not produce a result from PoCT and laboratory tests at day 1
2. Appropriateness of the modified Choyke screening questionnaire to identify patients with reduced renal function, measured as the number of patients with no risk factors who have a reduced renal function identified (eGFR<40) at day 1

Overall study start date
01/02/2016

Completion date

29/11/2016

Eligibility

Key inclusion criteria
1. Patients who are already having a blood test for U&Es (other assays will be excluded from the results)
2. The inclusion of non-English speaking patients will be made on a case-by-case basis
3. Those participants who are able to provide consent but are unable to read or write will be offered the opportunity for a witness to sign the participant consent sheet on their behalf
4. Over 18 years of age

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. Under 18 years of age
2. Pregnant patients
3. Those unable to provide consent

Date of first enrolment
07/09/2016

Date of final enrolment
26/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Pinderfields Hospital
Wakefield

United Kingdom
WF1 4DG

Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

Sponsor details
Rowan House
Aberford Road
Wakefield
England
United Kingdom
WF1 4EE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Research organisation

Funder Name
Yorkshire & Humber Academic Health Science Network

Results and Publications

Publication and dissemination plan
An e-poster was presented at the European Congress of Radiology (ECR), March 2017. Planned publication in a high-impact peer reviewed journal. The intention is to publish by November 2017.

Intention to publish date
01/11/2017

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?
Results article	results	26/07/2018		Yes	No
HRA research summary			28/06/2023	No	No