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A study to test a new way of more accurately measuring kidney function using fingerprick blood samples

Submission date
27/07/2022

Recruitment status
No longer recruiting

Registration date
28/07/2022

Overall study status
Completed

Last Edited
04/08/2022

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Blood tests used in kidney clinics estimate rather than measure kidney function. This means that they may not always be accurate. Here is also evidence that this inaccuracy affects some people more than others and may create health inequality. Clinical gold standard ways of actually measuring kidney function are time-consuming, expensive and have only limited availability. There is another gold standard test which involves injecting a dye and taking three or four blood tests over 5-6 hours to see how quickly the kidneys are removing this dye. This can be done in a routine way by injecting the dye when people come to clinic appointments and giving them a small kit that will allow them to take fingerprick blood samples at home later that day and post them back.

Who can participate?
Adult patients with chronic kidney disease attending renal outpatient appointments

What does the study involve?
Participants will be given a small injection of a dye when they come to the clinic and then have an extra teaspoon of blood with their usual clinic bloods and be shown how to use the fingerprick test kit. They will do the first fingerprick test in the clinic. They will take the kit home and do more tests 3, 4, and 5 hours later. Finally, they complete a feedback survey and everything is then posted back using a pack provided.

What are the possible benefits and risks of participating?
There is a small risk of allergic reaction as the dye contains iodine.

Where is the study run from?
Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2021 to August 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Darren Green, darren.green@nca.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
304466

Central Portfolio Management System (CPMS)
51877

Protocol serial number
S21KID09-S

Study information

Scientific Title
Improving the accuracy of chronic kidney disease monitoring using postal finger prick iohexol measured glomerular filtration rate

Study objectives
The primary aim of the study is to show that iohexol measured glomerular filtration rate (mGFR) can be undertaken with a high level of accuracy by healthcare professionals and patients together using microstamping test kits at home after an injection of iohexol at an outpatient appointment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2022, West of Scotland REC 4 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 22/WS/0016

Primary study design
Observational

Study design
Single-centre observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Patients with chronic kidney disease (CKD) where creatinine-based eGFR calculation may give spurious results

Interventions
Patients will be recruited from the renal outpatient department. Patients will receive a 5 ml bolus of Omnipaque followed by paired venous and fingerprick bloods 5 minutes post injection (time zero). Outpatients will have their appointment as usual and then go home with a home blood testing kit. Further fingerpick bloods will be taken by the patient at time points 3, 4 and 5 hours post-injection. The samples will be posted to the lab by the patient using an envelope provided in the kit. This can be done at any point in the 5 days after sample collection. An optional feedback survey will also be in the pack for completion and return. This is then the end of the study involvement.

Intervention Type
Other

Primary outcome(s)
Bland Altman comparison of fingerprick versus “gold standard” venous iohexol levels at time 0 using bias and P30 measurements

Key secondary outcome(s)
Percentage of participants in whom mGFR results differ from clinically used eGFR results to the extent that treatment is likely to have differed (e.g. drug dosing) had mGFR been used for clinical decision making at the time of study visit

Completion date
01/08/2023

Eligibility

Key inclusion criteria
Adult patients with CKD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Iodine intolerance
2. Unable to provide consent
3. Unable to perform fingerprick blood testing

Date of first enrolment
02/08/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Northern Care Alliance NHS Foundation Trust

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
An anonymised dataset will be produced and supplied as a supplement at the time of publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No