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Kidney function assessment with finger-prick blood tests in different people and different settings

Submission date
04/08/2020

Recruitment status
Recruiting

Registration date
09/09/2020

Overall study status
Completed

Last Edited
03/06/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys don't work as well as they should. It's a common condition often associated with getting older. It can affect anyone, but it's more common in people who are black or of south Asian origin.
GFR stands for Glomerular Filtration Rate, which is a measure of how well the kidneys are working. A nuclear medicine GFR test gives an accurate measure of overall kidney function.
Point of care (POC) testing with finger-prick blood monitoring is now available to assess kidney function with the finger-prick method, giving results in less than a minute without the additional cost of venous blood-taking, transportation and processing. Rapid availability of POC-Cr results could provide instant information about kidney health for high-risk groups in the black and minority ethnic (BAME) community (e.g. in faith-based settings).
In order to harness the benefits of POC-Cr self-monitoring, it is important to understand and interpret intra-patient variability in capillary blood results, potentially without need for complete alignment with laboratory tests. Self-monitoring may introduce increased anxiety and requirement for additional interaction with health care services.
Our overall aim is to develop and pilot a UK community-based screening and CKD monitoring program to address health inequalities in CKD, focusing on people of BAME.

Who can participate?
Adults over 18 years, either undergoing formal nuclear medicine glomerular filtration rate testing or has chronic kidney disease or at risk of chronic kidney disease.

What does the study involve?
In the first part of the study, participants will provide a drop of blood to test kidney function. Other information will be gathered from the hospital database. Some participants will go on to the second part of the study which involves participants taking measurements of their own using a portable device (StatSensor®) four times a day for 10 days.

What are the possible benefits and risks of participating?
No immediate benefit but it will help to provide information that may improve the care of

patients with kidney disease in the future.
There are no risks to taking part, other than minimal discomfort of the blood tests. The amount of extra blood that we take will not affect patients.

Where is the study run from?
King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2020 to June 2025

Who is funding the study?
British Renal Society

Who is the main contact?
Danilo Nebres, d.nebres@nhs.net
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
263206

Protocol serial number
CPMS 45543, IRAS 263206

Study information

Scientific Title
Renal function Assessment with Point of care creatinine testing In Diverse populations (RAPID)

Acronym
RAPID

Study objectives
1. Thresholds of point-of-care creatinine can be identified to be used for CKD diagnosis in people of different ethnicities
2. Serial home point-of-care creatinine by patients is accurate and feasible

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2020, London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8063; bromley.rec@hra.nhs.uk), ref: 20/LO/0620

Study design
Observational cross-sectional

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Renal failure

Interventions
This is a multi-centre cross-sectional and prospective longitudinal cohort study. Primary objectives include assessment of Point of Care Creatinine (POC-Cr) accuracy and precision in order to define thresholds for screening which identify individuals with Chronic Kidney Disease (CKD) (Study A) and exploration of variability and patient acceptability of self-monitoring of POC-Cr including Ease or Simplicity of Use (Study B).

375 participants (including at least 125 of African/African-Caribbean ancestry and 125 Asian background) having venous serum creatinine and 99mTc-DTPA nuclear medicine testing will be recruited to a cross sectional study (Study A).

40 patients with CKD or at risk of kidney disease will be recruited to a one week longitudinal study (Study B).

Study A: POC-Cr will be assessed on a drop of capillary whole blood by the research team and venous serum creatinine for routine care (Isotope Dilution Mass Spectrometry (IDMS) Traceable Enzymatic assay) and 99mTc-DTPA glomerular filtration rate testing will be extracted from hospital laboratory databases.

Study B: Participants will be trained to use the StatSensor® by the research team and time taken recorded. Participants will be taught how to perform quality controls, finger prick lancing and sample analysis. All sample results will be digitally recorded by the device and downloaded after the device is returned. Participants will be asked to self-monitor four times per day (first thing in

morning, midday, before evening meal/early evening, before bed) and each test recorded in a paper diary or electronically as desired. Details reported will include time of test, test success, device and non-device failures (test results, missed testing and reasons for missed test (e.g. forgot, did not want to test) and adverse events (e.g. pain, infection, pre-syncopal or syncopal episode).

Intervention Type
Other

Primary outcome(s)
Measured at a single time point:
Study A:
1. Estimated glomerular filtration rate (eGFR) measured using Point of care – creatinine (POC-Cr)
2. Formal GFR assessment (Measured GFR (MGFR) and Venous Creatinine) measured using venous creatinine results from the laboratory and the MGFR results from the nuclear medicine department
Study B:
1. Test success rate, safety, training time, patient experience and acceptability of serial capillary POC-Cr testing measured on the final visit using SUTAQ questionnaire

Key secondary outcome(s))
Study B:
Measured during baseline and final visit:
1. Capillary creatinine measured using Point of care – creatinine (POC-Cr)
2. Venous serum enzymatic creatinine concentrations (serum Cr) measured using venous creatinine results from the laboratory

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Willing to complete all study procedures
3. Patients undergoing formal nuclear medicine glomerular filtration rate testing (Study A only)
4. Has Chronic Kidney disease (CKD) KDIGO criteria or is at risk of CKD due to heart disease or diabetes as determined by physician (Study B only)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Any condition which would make finger prick contraindicated e.g. severe skin conditions, bleeding disorder
3. Study A: If formal GFR testing has been requested only because estimated GFR is not considered to reflect true GFR (e.g. liver disease)

Date of first enrolment
21/07/2020

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
The Royal London Hospital
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
British Renal Society

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The data is being stored on a research-specific database which is GDPR compliant (REDCap). It is also being stored on EDGE.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 8.0	29/10/2024	19/11/2024	No	No