ISRCTN11076307 https://doi.org/10.1186/ISRCTN11076307

Home monitoring of kidney function in cancer patients: assessing acceptability and clinical benefit

Submission date 18/06/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/07/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/01/2025	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Current research suggests that people with reduced kidney function may have an increased risk of cancer, for reasons that are not totally clear. When patients with reduced kidney function develop cancer, the treatment options can be limited due to concerns over causing more damage to already damaged kidneys and because the cancer drugs haven't been tested in this type of people. Currently cancer clinical trials exclude people with reduced kidney function from taking part and receiving experimental drugs. This can lead to further reduction in treatment options for people with reduced kidney function and cancer. This study aims to see if monitoring kidney function more frequently in people receiving anti-cancer treatments (that can affect the kidneys) picks up problems with the kidneys quicker and whether it's acceptable to patients to monitor their kidney function in this way at home.

Who can participate?
Patients aged 18 and over receiving anti-cancer treatment

What does the study involve?
The study is split into 2 parts. Part A aims to enrol 12 patients to use the device at home when they are receiving their treatment. Participants take a small sample of blood and use a small device to check their kidney function. Using an app on their smartphone they send their result to the researchers who look for evidence of kidney damage. In Part B of the study 30 patients are recruited to use the device and the researchers compare them with 30 patients who are receiving standard kidney monitoring.

What are the possible benefits and risks of participating?
There are no benefits to participants in taking part in the study. The blood sampling will cause some localised tenderness or a small bruise but otherwise, there are no risks to taking part in this study.

Where is the study run from?
The Christie NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2019 to June 2025

Who is funding the study?
University of Manchester (UK)

Who is the main contact?
Dr Leanne Ogden
Leanne.ogden@digitalecmt.org

Contact information

Type(s)
Public

Contact name
Dr Leanne Phillips

Contact details
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL
+44 (0)7875012051
Leanne.phillips@mft.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
255751

Protocol serial number
R119106

Study information

Scientific Title
Home monitoring of creatinine in cancer patients: assessing acceptability and clinical benefit

Acronym
In-Home

Study objectives
Intensive monitoring of kidney function in patients receiving anti-cancer treatments will lead to earlier detection of acute kidney injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/05/2019, NHS REC Greater Manchester East (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8009; Email: a.ecclestone@nhs.net), IRAS: 255751, REC ref: 19/NW/0164

Primary study design
Interventional

Study design
Single-centre interventional randomised controlled trial with a feasibility run-in

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Nephro-oncology

Interventions
Intensive, home-monitoring of creatinine compared to standard renal function monitoring in patients receiving anti-cancer treatments. Randomisation will be 1:1 using an online randomisation tool.

Part A aims to enrol 12 patients to use the device at home when they are receiving their treatment, 3 times per week for 4 weeks, this is in addition to their standard of care monitoring. There is no change to the treatment they are receiving. Participants will take a small sample of blood and use a small device to check their kidney function. Using an app on their smartphone they will send their result to the researchers who will look for evidence of kidney damage.

Part B of the study will have 2 arms. The intervention arm will use the device at home to check their kidney function 3 times per week for 6 weeks. This is in addition to the standard of care monitoring and treatment. The standard of care arm will have standard monitoring during their treatment. Neither arm will have a change to their planned treatment. There is no follow-up period.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
StatSensor Xpress creatinine monitoring system

Primary outcome(s)
Part A: Patient acceptance of intensive home-monitoring of whole-blood creatinine, assessed using:
1. Questionnaire and interview
2. Absolute number of creatinine readings received - expected vs actual
3. Time sample taken vs. time expected to take
4. Value sent/received vs. value on device (when downloaded at the end of the study period)
Assessed at Week 4

Part B: Potential for earlier diagnosis of AKI/change in renal function with intensive home-monitoring of whole-blood creatinine, assessed using:
1. Time from beginning of current cycle treatment to detection of AKI by amended algorithm or clinician/laboratory reading
2. Severity of AKI at detection (as per Kidney Disease Improving Global Outcomes AKI Work Group staging)
3. Overall change in renal function from beginning to end of study period
Assessed throughout study period

Key secondary outcome(s)
Part B:
1. Kidney function assessed at the beginning and end of the study (Weeks 1 and 6)
2. Quality of life assessed using medical outcomes study short form 36 (SF-36) questionnaire at Week 6
3. Adherence of patients to intensive home monitoring regimen, assessed using:
3.1. Absolute number of creatinine readings received
3.2. Time sample taken vs. time expected to take
3.3. Value sent/received vs. value on device (when downloaded at the end of the study period)
Assessed at Week 6

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Provision of signed and dated, written informed consent prior to participation in the study
2. Aged at least 18 years
3. Receiving treatment for cancer with potentially nephrotoxic anti-cancer therapies (according to the judgement of the CI)
4. Individuals whose medical team consider to be medically stable and able enough to take part or designated carer who would be able to perform the tasks required
5. Willingness and ability to self-monitor creatinine using device at home or have a designated carer who would be able to perform the tasks required. Part A device will be the NovaBiomedical StatSensor®
6. Access to smartphone and willingness to use, without reimbursement of any potential additional costs incurred, their iOS/Android device for the collection and transmission of information

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Being an employee, or closely linked with an employee, of the device company
2. Judgment by the Investigator that the individual should not participate if they are unlikely to comply with study procedures and requirements
3. WHO performance status > 2
4. Pregnancy

Date of first enrolment
01/06/2019

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Christie NHS Foundation Trust
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Leanne Phillips (Leanne.phillips@mft.nhs.uk).
1.1 Type of study
Single centre, randomised clinical trial to assess the acceptability and clinical benefit of home monitoring of creatinine by cancer patients
1.2 Types of data
Quantitative data - creatinine results from home-based device and laboratory results; urine dipstick and protein creatinine ratio; blood pressure; weight; medications.
Qualitative data – Participant and clinician questionnaire and interview
1.3 Format and scale of the data
Approximately 20 creatinine readings per study participant captured in encrypted electronic form.
Baseline data capture in paper workbook and consolidated into excel workbook
Participant feedback from paper-based questionnaires.
Approximately 72 particpants to be recruited (30 will be randomised in to the non-device group therefore will not be sending in creatinine readings)
2. Data collection / generation
2.1 Methodologies for data collection / generation
Creatinine measurements will be collected by study participants using a point of care creatinine device in their home. These measurements will be transferred to a secure Microsoft Azure environment.
Other data capture in paper workbook and consolidated into excel workbook
2.2 Data quality and standards
Participant measured creatinine readings will be compared with the data downloaded directly from the point of care analyser to assess the accuracy of reporting. each device will be calibrated by the study participant prior to use and has been calibrated with the hospital laboratory.
3. Data management, documentation and curation
3.1 Managing, storing and curating data.
A mobile application will be used to capture creatinine readings from a point of care device to

storage in Microsoft Azure environment. These data files are backed up and data is retained or the duration of the study.
3.2 Metadata standards and data documentation
The aim of the study is to publish the results of the study, this would include summary data
3.3 Data preservation strategy and standards
Anonymised data will be archived with associated meta data
4. Data security and confidentiality of potentially disclosive information
4.1 Formal information/data security standards
The Digital Experimental Cancer Medicines Team have an information security policy that will be followed.
4.2 Main risks to data security
• Data Collection:
Participant identification from collected data - the unique participant ID used in the study is pseudonymised and no identifiable data is collected. Likelihood of risk occurring is low
Participant identification by the creatinine images sent in if they contain personal identifiable information in error - all images will be reviewed by the study team and any image that is at risk of identify the patient will be deleted. Patients will receive training on how to use the app and specifically how to take an image of the creatine device. Likelihood of risk occurring is low
• Data Access:
MRC Template for a Data Management Plan, v01-1, 10 March 2017 2
Data is transmitted and stored in encrypted form. Access to the data is controlled and can only be authorised by the study data manager.
5. Data sharing and access
5.1 Suitability for sharing
The purpose of this research and the consent obtained extends only to establishing that the device can be used effectively for home-based creatine readings. Data will be pseudonymised during the study. At the end of the study the data will be anonymised to enable data sharing and protection of patient privacy.
5.2 Discovery by potential users of the research data
The results of the work will be published in Open Access journals
5.3 Governance of access
The Sponsor is the Data Controller and makes all decisions on data sharing
5.4 The study team's exclusive use of the data
There is no exclusivity by the study team over this data. Requests for sharing within the participant consent agreement will be considered by the Sponsor
5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions
Requests for sharing within the patient consent agreement will be considered by the Sponsor
5.6 Regulation of responsibilities of users
Access will be considered for external users to anonymized data under a data agreement that ensures compliance with the original patient consent agreements
6. Responsibilities
The Sponsor is accountable for the information in this study. The Sponsor may delegate information control responsibility to the Chief Investigator
7. Relevant institutional, departmental or study policies on data sharing and data security
Policy URL or Reference
The University of Manchester Data Protection Policy
8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details
Paul Fitzpatrick
Paul.fitzpatrick@digitalecmt.org

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file			16/08/2019	No	No